QUALITY MANAGEMENT

PROGRAM PLAN

FOR

REGION 10

DOCUMENT CONTROL NUMBER

RQMP-001/96

U.S. ENVIRONMENTAL PROTECTION AGENCY

1200 SIXTH AVENUE

SEATTLE, WASHINGTON 98101

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ACRONYMS

CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CLP	Contract Laboratory Program
CSIS	Compliance Sampling Inspection
DMR	Discharge Monitoring Report
DQOs	Data Quality Objectives
ESAT	Environmental Services Assistance Team
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GSA	General Services Administration
I & M	Inspection & Maintenance
IAGs	Inter-Agency Agreements
NAMS	National Air Monitoring System
NERL	National Environmental Research Laboratory
NESHAPS	National Emissions Standards for Hazardous Air Pollutants
NIST	National Institute of Standards and Technology
NPDES	National Pollution Discharge Elimination System
NSPS	New Source Performance Standards
OAQ	Office of Air Quality
OCI	Office of Criminal Investigations
OEA	Office of Environmental Assessment
OECL	Office of Environmental Cleanup
OIG	Office of the Inspector General
OMP	Office of Management Programs
OSC	On-Scene Coordinator
OWCM	Office of Waste and Chemicals Management
OW	Office of Water
PAIs	Performance Audit Inspections
PE	Performance Evaluation
QAMS	Quality Assurance Management Staff (Hq)
RCRA	Resource Conservation and Recovery Act
RPM	Remedial Project Manager
RPO	Regional Project Officer
RQMP	Regional Quality Management Program
RQPM	Regional Quality Program Manager
SARA	Superfund Amendment and Reauthorization Act
SEA	State-EPA Agreement
SLAMS	State/Local Air Monitoring Station
SO	State/Field Office
SOP	Standard Operating Procedure
TSCA	Toxic Substances Control Act
QA	Quality Assurance
QAPjP	Quality Assurance Project Plan
QC	Quality Control
QM	Quality Management
QMPP	Quality Management Program Plan
WP	Water Pollution
WS	Water Supply

GLOSSARY

EDCA Environmental data collection activities include any laboratory or field data generation activity or investigation involving the determination of biological, chemical, or physical factors related to the environment. Some examples are: determining the presence or absence of pollutants in waste streams; health and ecological effect studies; clinical and epidemiological investigations; engineering and process evaluations; studies or measurements of pollution transport, etc.

QAMS The Quality Assurance Management Staff is the Agency office, located at Headquarters, that is the focal point for quality assurance policy and is responsible for developing QA requirements and overseeing Agency-wide implementation of the QA Program.

The term Regional Program Managers shall be used in this document to include all supervisory and management personnel (e.g., Unit Chief or Office Director).

RPMs The term Regional Project Managers shall be used in this document to include all personnel responsible for overseeing environmental data collection activities. This shall include, but not be limited to: Remedial Project Managers, Work Assignment Managers, Delivery Order Officers, On-Scene Coordinators, permit writers, compliance personnel, investigators, project officers, etc.

RQMP The Regional Quality Management Program has the delegated authority for managing and overseeing regional quality management policies, practices, and requirements. The RQMP is also responsible for overseeing the implementation of the Agency-wide QA program, including grants, contracts, formalized and interagency agreements.

1.0 QUALITY MANAGEMENT PROGRAM PLAN IDENTIFICATION FORM

Document Title: Quality Management Program Plan for Region 10

Document Control Number: RQMP-001/96

Organization Title: EPA Region 10

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Plan Coverage:

This plan covers all monitoring and measurement activities mandated through EPA regulations and memoranda. This includes all internal and external environmental data generated by activities conducted through regional monitoring programs, grants, contracts, interagency, and cooperative agreements.

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2.0 INTRODUCTION

Region 10 is strongly committed to good science and aggressive quality management (QM) practices. This commitment is consistent with the goals of the Administrator's Quality Assurance (QA) Policy Statement and EPA Order 5360.1.

Region 10 has already developed and integrated quality management (QM) practices into monitoring and measurement activities within its purview. These QM practices are specifically designed to generate and process data of known and appropriate quality in a cost-effective manner.

The purpose of this document is to define and describe the QM, QA, and Quality Control (QC) policies and responsibilities required by Region 10, in concurrence with the Agency's mandated QM program. The document is designed to provide a logical connection between Agency QM policy and the implementation of such policies in Region 10. This document is intended to assist Region 10 Project Officers and Managers in the uniform implementation of QM, QA, and QC requirements for Region 10 Monitoring Programs, Grants, Contracts, Cooperative Agreements, and Interagency Agreements.

3.0 REGIONAL QUALITY MANAGEMENT POLICY

It is the policy of Region 10 that there shall be sufficient Quality Management (QM) activities conducted within the Region to ensure that all environmental data generated and processed shall be: scientifically valid, of adequate statistical quantity, of known precision and accuracy, of acceptable completeness, representativeness, and comparability, and where appropriate, legally defensible. This goal can be achieved by ensuring that adequate QM steps and procedures are used throughout the entire monitoring process (from initial study planning through data usage).

Regional policy shall comply with EPA Order 5360.1 which requires a Quality Assurance Project Plan for all environmental data collection activities. Environmental data collection activities are defined as the collection or generation of any chemical, physical, or biological measurements. EPA Order 5360.1 requires compliance for all environmental data collection activities in which data is generated by or for the Agency. EPA

Order 5360.1 is attached in Appendix A.

A. Specifically it is the policy of Region 10 that:

1. **Each monitoring program that generates environmental data shall develop and implement a QA Project Plan (QAPjP) addressing the major elements contained in appendices B & C and shall ensure that adequate resources (both monetary and staff) are provided to support the QA objectives of the QAPjP. The project plan should specify the detailed procedures required to assure the generation of quality data. All QA project plans must be approved prior to data collection and/or scheduling of laboratory space. The Regional Quality Management Program (RQMP) can assist with plan reviews and concur on the approval/disapproval of all QAPjPs. Special exemptions can be requested through the RQMP for emergencies or special investigations. Special situations shall still require the preparation and approval of a QAPjP after the field event. The occurrence of special situations is expected to be limited and is not to be a routine operational procedure.**

2. **All environmental data generated shall be of known and acceptable quality. The data quality information developed with all environmental data shall be documented and available.**

3. **All Regional monitoring programs shall ensure that acceptable QM requirements are included and implemented in all applicable external monitoring activities funded by the EPA.**

4. **The intended use(s) of the data shall be defined before the data collection effort begins, so that appropriate QM measures may be applied to ensure a level of data quality commensurate with the monitoring objectives. The determination of this level of data quality shall also consider the prospective data needs of secondary users. Data Quality Objectives (DQOs) shall be established to ensure the utility of monitoring data for its intended use and as guidance for preparation of QA project plans. The Programs shall be responsible for determining the appropriate QM practices, using the DQO process for each QAPjP. The intended data uses, level of quality, specific QM activities, and data acceptance criteria needed to meet the data quality needs of these uses shall be described in each monitoring activity's QA project plan.**

5. Quality assurance activities shall be designed in the most cost effective fashion possible, without compromising data quality objectives.

6. The development and maintenance of acceptable State QA programs shall be integrated, as appropriate, into the overall State-EPA Agreement ("SEA") process.

The Regional Administrator has the overall responsibility for the development, implementation, and continued operation of the Regional QM Program. The authority and responsibility for managing the QM activities within the Region shall be assigned to the Regional Quality Program Manager (RQPM). To ensure that the Region's QM policy is uniformly applied to the generation and processing of all environmental data, a Regional Quality Management Program (RQMP) shall be established and maintained. The Regional Quality Program Manager shall act as Manager of the Regional Quality Management Program. The RQMP shall function as a central quality management authority organizationally independent of the programs supported, i.e., environmental data generators and users.

B. The Regional QM Program shall meet the following requirements:

1. The RQMP shall be the technical and central management authority for all QM matters within the Region. The RQMP shall review, comment, and concur on all Regional QA Project Plans. The RQMP shall be the focal point for interaction between the Quality Assurance Management Staff (QAMS), NERL's, National Program Offices, state, local, private, and other Federal agency QA personnel on Quality Management issues to ensure that agency QM requirements are met.

2. The RQMP shall be adequately organized and staffed, and able to request specific technical expertise primarily from the technical staff of the Office of Environmental Assessment or from other Office programs when specific expertise is needed, i.e. Radiation, Health Physics, etc. After being requested through appropriate management, the technical expert shall function as part of the RQMP.

3. Region 10 Project Officers (RPMs) shall inform the RQMP of activities relating to QM within their specific monitoring programs and facilitate development and implementation of QA Project Plans.

4. Facilities, equipment and services that, directly or indirectly, have an impact on data quality or integrity

shall be routinely inspected and maintained where appropriate (as outlined in facilities plan). The facilities plan shall identify the parties responsible for conducting routine inspections.

5. Data processing shall be documented, reviewed, and revised as required by the Regional Quality Management Plan or Agency mandates and guidelines. Data shall be validated according to specific criteria, which shall follow EPA guidelines and regulations.

6. When data falls outside acceptable limits, the appropriate management official (Regional Project Manager, Regional Program Manager, etc.) shall, with the assistance of the RQMP develop and implement a mechanism for corrective action. This will assure that any deficiencies in data generation activities, detected by the QM program, can be corrected in a timely manner.

7. The RQMP shall submit an annual Region 10 QM Report and Work/Audit Plan, to the Regional Administrator and the Director of the QAMS, for review and approval. The annual Region 10 QM Report and Work/Audit Plan will be used by the QAMS in preparation of the annual Agency QM Report. The annual Agency QM Report will be sent to the Administrator.

8. The Region 10 QM Program Plan shall be reviewed at least annually, by the RQMP, and updated as required. Significant revisions to the Region 10 QM Program Plan shall be submitted to the Regional Administrator, OEA Office Director and the QAMS for review and concurrence or approval.

4.0 EPA POLICY ON FRAUD, WASTE, AND ABUSE

It is the responsibility of Region 10 managers and supervisors to inform EPA employees of their responsibilities concerning Federal Fraud, Waste, and Abuse regulations, and of their responsibilities under the Agency's Standards of Employee Conduct. The following information is a summary of Federal requirements as they pertain to EPA employees:

A. Paragraph 2.b, Chapter 3, of EPA Manual 6500, "Functions and Activities of the Office of the Inspector General" (January 22, 1985) states:

> All employees of the Agency, within the limits of their

authority and duties, are responsible for (1) fostering the enforcement of laws, executive orders, regulations, and other applicable directives; (2) maintaining high standards of ethical conduct; and (3) promoting efficiency and effectiveness in the administration of the Agency's programs and activities.

These responsibilities require that all employees promptly report instances of and information on any known or suspected violation of law, rules, or regulations; mismanagement; gross waste of funds; abuse of authority; or substantial and specific danger to the public health and safety. Employees should report such instances to their supervisors, or if necessary, directly to the Office of the Inspector General (emphasis added).

As stated in Section 7c of the Inspector General Act, action shall not be taken or threatened against any employee as a reprisal for making complaints or disclosing information to the Office of the Inspector General (OIG) unless the complaint was made or the information disclosed with the knowledge that it was false or with willful disregard for its truth or falsity.

In accordance with Section 7b of the Inspector General Act, the identity of an employee, other than a supervisor or manager acting in his or her official capacity, who comes forth with a complaint or information by contacting the OIG shall be kept confidential. Exceptions can be made to this general rule where (1) the employee consents to the release of his or her name, or (2) the Inspector General personally determines such disclosure is unavoidable during the course of the investigation. The provisions of confidentiality under Section 7b is limited to EPA employees who directly contact the OIG.

A telephone hotline, maintained in the OIG, is available to all EPA employees and the public for reporting Agency activities involving fraud, waste, or mismanagement.

Washington, DC OIG Hotlines:
(800) 424-4000
(202) 260-4977

Seattle, WA OIG Hotline:

(206) 553-1273

B. The Agency's standards-of-conduct regulations for EPA employees are stated in 40 CFR Part 3. The EPA Region 10 library has a current copy of 40 CFR Part 3.

4.1 Supplying of PE Materials to Suspended or Debarred Entities

In order to assure the scientific quality of EPA's decision making, and in order to more completely protect the public's health, welfare, and the environment, it shall be Regional policy not to supply performance evaluation materials to parties that are suspended, debarred or excluded parties (voluntarily or otherwise). This shall mean that any company, individual or other parties listed in the document entitled, "GSA Lists of Parties Excluded From Federal Procurement or Nonprocurement Programs" shall not be eligible to receive, directly or indirectly, any performance evaluation samples provide by the EPA. This restriction shall include all water supply (WS), water pollution (WP), discharge monitoring report (DMR) or other performance evaluation materials.

The "GSA Lists of Parties Excluded From Federal Procurement or Nonprocurement Programs" is published on a periodic basis by the General Services Administration. Copies of this document are usually available in the Office of Regional Counsel or through the Regional Contract Officer. A subscription to the "Lists" is available through GSA by calling (202) 501-3566 or (202) 501-4704.

5.0 QUALITY MANAGEMENT RESPONSIBILITIES

5.1 Regional Program Identification

Identification of each Regional program role covered by the QM requirements is described below:

The Office of Environmental Assessment (OEA) has management responsibilities for the Regional Quality Management program. OEA provides specialized technical support; conducts special studies and analyzes environmental samples; processes, analyzes, and recommends the use to be made of environmental data by the program offices. OEA overviews some external environmental monitoring. OEA shall prepare QA project plans and/or Standard Operating Procedures (SOP) for all monitoring and measurement activities it conducts. These plans shall be developed according

to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Air Quality (OAQ) has the lead program management responsibilities for the SLAMS/NAMS, Stationary Source (NSPS/NESHAPS), Mobile Source (I & M) and part of the TSCA programs. OAQ manages a portion of the Regional Federal grants and contract fund processes. OAQ ensures that QM matters are reflected in budgets, program plans, and work/operating plans. OAQ serves as the technical/program authority for all air environmental monitoring activities within the geographical boundaries of Region 10. Data arising from these programs are the product of efforts, both internal and external to the Region. OAQ overviews external environmental monitoring programs.

The Office of Environmental Assessment (OEA) provides the OAQ with technical assistance relevant to monitoring and data processing activities. This includes system and performance audits on air monitoring activities, inspections of stationary and mobile sources, and coordination of the Performance Evaluation Studies. QA project plans for special ambient studies conducted by the Region will be prepared by OEA. QM/QA program/project plans developed by State/Local Agencies shall be approved by the OAQ with concurrence from the RQMP. These plans shall be reviewed annually and revised as needed. QA program/project plans shall be developed according to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Ecosystems and Communities (OEC) has the program management responsibilities for the Pesticides and NEPA programs. OEC ensures that QM matters are reflected in budgets, program plans and work/operating plans. OEC serves as the technical/program authority for all of the toxics and NEPA monitoring activities within the geographical boundaries of Region 10. Data arising from these programs are the product of efforts, both internal and external to the Region. OEC overviews external environmental monitoring activities.

The Office of Environmental Assessment (OEA) provides assistance to the OEC relevant to monitoring and data processing activities and through the coordination of the Regional Pesticide Performance Evaluation Studies. OEC shall develop QA project plans for FIFRA monitoring activities they conduct. QM/QA program/project plans developed by State/Local Agencies shall be approved by the

OEC with concurrence from the RQMP. These plans shall be reviewed annually and revised as needed. QA program/project plans shall be developed according to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Environmental Cleanup (OECL) has the program management responsibilities for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA and SARA); and Emergency Response Programs. OECL ensures that QA matters are properly reflected in budgets, program plans, contracts, permits, Interagency Agreements (IAGs) and work/operating plans. OECL serves as technical/program authority for all Superfund and Emergency Response environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OECL overviews external environmental monitoring programs.

The Office of Environmental Assessment provides the OECL with technical assistance relevant to the collection and analyses of environmental samples. This includes Regional management of the Contract Laboratory Program (CLP) and Environmental Services Assistance Team (ESAT) Contract; review of CLP data; and preparation of QA project plans for Superfund monitoring activities that OEA conducts. OECL shall develop QA project plans for all Superfund and Emergency Response monitoring activities they conduct. QM/QA program/project plans developed by State/Local Agencies shall be approved by the OECL with concurrence from the RQMP. QA program/project plans shall be developed according to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Waste and Chemicals Management (OWCM) has the program management responsibilities for the Resource Conservation and Recovery Act (RCRA); Toxic Substance Control Act (TSCA), and the Emergency Prevention and Community Response Act (EPCRA). OWCM is responsible for permitting and compliance, as well as, enforcement for facilities storing hazardous waste. OWCM manages Federal grants and contract funds. OWCM serves as technical/program authority for all RCRA environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OWCM overviews external environmental monitoring programs.

The Office of Environmental Assessment (OEA) provides the OWCM with technical assistance relevant to monitoring and

data processing activities. This includes system audits on monitoring activities, and compliance inspections and preparation of QA project plans for RCRA monitoring activities that OEA conducts. OWCM shall develop QA project plans for all RCRA and TSCA monitoring activities they conduct. QM/QA program/project plans developed by State/Local Agencies shall be approved by the OWCM with concurrence from the RQMP. These plans shall be reviewed annually and revised as needed. QA program/project plans shall be developed according to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Water (OW) has the program responsibilities for the public water supply; ambient surface and groundwater; underground injection control; estuarine waters; off-shore discharge; and domestic and industrial wastewater treatment programs. OW is responsible for permitting and compliance, as well as, enforcement for water stationary sources, domestic and industrial treatment facilities. OW manages Federal grants and contract funds. OW ensures that QA matters are properly reflected in budgets, program plans, contracts, permits, Interagency Agreements (IAGs) and work/operating plans. OW serves as the technical/program authority for all water related environmental monitoring activities within the geographical boundaries of Region 10. The data arising from these programs are the product of efforts, both internal and external to the Region. OW overviews external environmental monitoring programs.

The Office of Environmental Assessment (OEA) provides the OW with technical assistance relevant to monitoring and data processing activities. This includes oversight of State/Local fixed ambient water monitoring networks; special ambient studies; system and performance audits on water and waste field monitoring; and laboratory operations; NPDES compliance inspections and oversight inspections (CSIs and PAIs). OEA shall prepare QA project plans for all special studies, and compliance monitoring/inspections it conducts. OW shall develop QA project plans for data collection activities they conduct and require permittees to develop and maintain QA project plans for all permits. QM/QA program/project plans developed by State/Local Agencies shall be approved by the OW with concurrence from the RQMP. QA program/project plans shall be prepared according to National and Regional QM requirements and specifications (Appendices B, C, & D).

The Office of Criminal Investigations (OCI) is responsible for conducting investigations of criminal violations within Region 10. OCI prepares criminal cases and takes enforcement actions to attain compliance with environmental laws and EPA regulations. This involves surveillance activities, file searches, and the collection of environmental samples. The Office of Criminal Investigations will prepare QA project plans for environmental monitoring activities it conducts. These plans shall be developed according to appropriate National and Regional QM requirements and specifications (Appendices B, C, & D).

The State/Field Office (SOs) (Alaska, Idaho, Oregon, Washington) represent the Regional Administrator on State matters and provide leadership, coordination, and liaison with the officials of each State's environmental agency, Tribes, and other Federal, State, and local organizations. SOs perform program specific functions according to approved work plans as implementation work, inspections, permits, outreach, Superfund site management, ecosystem/geographic work, and multi-media coordination. Actual assignments to each office may vary according to the needs of the State and the nature of EPA activities in each state as documented in the work plans. The work plans may require collection of environmental samples. The State Offices shall be responsible for preparing QA project plans for each data collection activity they conduct. These plans shall be developed according to appropriate National and Regional QM requirements and specifications (Appendices B, C, & D).

5.2 Multiple Office Responsibilities

The Region has some projects in which responsibilities are split between more than one Office. This section will briefly discuss the responsibilities for these projects.

A. Regional Groundwater Data Management Order

In 1989, the Region adopted the Regional Groundwater Data Management Order (R10 7500.1) to establish consistent procedures for organizing, reporting, transmitting, storing and retrieving groundwater data. This order applies to all groundwater data collection activities carried out by EPA staff or EPA contractors, including research and development, enforcement and permit issuance. The responsibilities defined in this order are summarized below. For specific details refer to the Order.

1. Office Directors shall be responsible for the implementation of this order within their respective Offices.

2. The OEA Laboratory shall encode and input the results of all groundwater sample analysis performed at the Laboratory into the Laboratory Sample Data Management System. The Laboratory shall also enter contract laboratory data for projects conducted directly by EPA staff.

3. OEA shall provide guidance and training, as requested, to ensure that data is properly encoded according to specifications contained in the Order.

4. OEA shall be responsible for determining the disposition of the data received by EPA, and transferring data to the appropriate EPA data management system.

5. OEA shall code and enter historical data, and data collected under ongoing agreements, as allowed by time and resources.

6. Sampling plans and QA plans shall be reviewed for compliance with this Order, prior to approval.

7. OECL, OCWM, OW, OEC and SO's shall, where appropriate, require that all groundwater data management procedures are complied with as described in this Order.

B. Regional Environmental Monitoring and Assessment Program

The Regional Environmental Monitoring and Assessment Program (REMAP) is ....[to be added]

5.3 Assignment of Responsibilities

In order to properly manage the QM activities of environmental monitoring programs within Region 10, all QM/QA management responsibilities shall be assigned to the RQMP. The Manager of the RQMP shall be under the administrative management direction and support of the OEA Director. The RQMP shall function independent of the programs it supports. The organizational structure is shown in Figure 1.

A. Regional Quality Management Program Responsibilities

The RQMP, located in the Quality Assurance and Data Unit (QADU) of the Office of Environmental Assessment, has the responsibility for managing the Region 10 QM Program. The RQMP Manager shall serve as the Unit chief of the QADU and as the Regional QM Program Manager (RQPM). The following list enumerates the responsibilities of the RQMPM or their designated staff:

1. **The official Regional contact for all QM matters in the Region.**

2. **Respond to QM/QA needs, resolve problems, and answer requests for guidance or assistance.**

3. **Assist in the development of Regional QA Project Plans with Regional Project Managers, managers and others.**

4. **Review and concur on the approve/disapprove all Regional QA Project Plans required by EPA Order 5360.1. Review implementation of selected QA plans and adequacy of the data generated from a quality perspective.**

5. **Assure that Agency and Regional QM Program requirements are integrated into all Regional contracts, Interagency Agreements, grants, and the overall State/EPA Agreement process and grants.**

6. **Assist States in the development and implementation of QM/QA Program and Project Plans (see below).**

7. **Coordinate and/or conduct System and Performance audits of selected environmental monitoring programs.**

8. **Submit annual QM Status Report and Work Plan to Regional Management and QAMS.**

9. **Participate in QAMS review of Region 10 QM Programs.**

10. **Provide training on QM/QA policies and procedures.**

An important part of the QM program in Region 10 has been the excellent interaction of the Region with State and local agency personnel. Each State's environmental agency has developed an approved QA Program Plan, and appointed a QA Officer to interact with the RQMP. The Region and states will work to ensure that all environmental data generated and processed by the states, for agency use, shall be of known and documented quality.

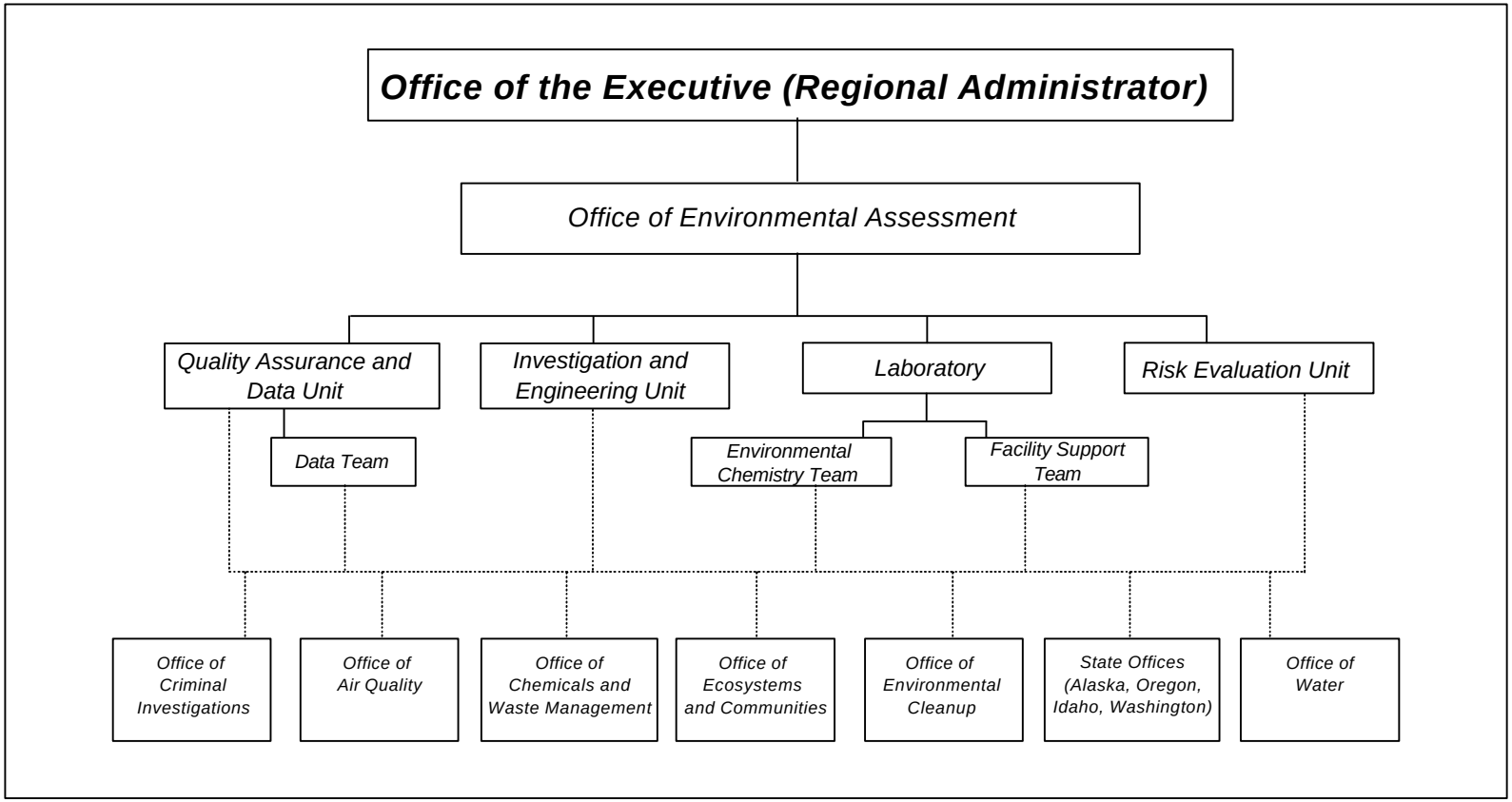


Figure 1. Organizational Structure of EPA Region 10 QMP.

Note: Administrative Management responsibilities are represented by a solid lines Interactions between Regional Programs are represented by dashed lines. PM/PO: Project Managers/Project Officers; TS: Technical Specialists.

B. Technical Specialists Responsibilities

To ensure that a satisfactory level of QM/QA capability is maintained in Region 10, the RQMP shall be able to request technical assistance from technical specialists within the OEA or from other Office programs when special expertise is needed. These personnel have expertise in specific areas such as: air, water, drinking water laboratory certification, compliance monitoring, field operations, chemistry, microbiology, biology, and data processing. After being requested, through appropriate management, the specialists shall function as part of the RQMP.

The specific duties which shall be assigned to the OEA Technical Specialists are as follows:

1. Assist the RQMP with technical aspects of QA as related to their expertise in air, water, toxic substances, hazardous waste, chemistry, biology, microbiology, field operations and data operations.

2. Identify QA needs, resolve problems, and answer requests for guidance or assistance in their area of expertise.

3. Conduct and/or participate in on-site field and laboratory system audits; performance audits; and assist Office of Regional Counsel in conducting audits and evaluations.

4. Conduct compliance monitoring inspections.

5. Carry out Region 10 requirements for the Drinking Water Laboratory Certification Program.

6. Conduct system and performance evaluations of all special studies and SLAMS/NAMS monitoring networks.

7. Inform RQMP of the need for new or improved methods.

8. Participate in technical assistance and training of State/Local, and private laboratory personnel in EPA methods, instrumental, and QA requirements.

9. Review subordinate's and associates' data for QA before transmittal to the submitter and data system.

10. Interact with other Agency programs on technical problems particularly as related to QM, QA, methods, instrumentation, and new programs.

C. Regional Program Managers Responsibilities

Regional Program Managers are responsible for ensuring that their internal and external monitoring projects are in accordance with Agency QM policy.

Some of the key responsibilities of Regional Program Managers are:

1. **Establish planning policies to ensure that QM/QA matters are reflected in monitoring budgets, program plans, grants, contracts, Interagency Agreements and operating plans.**

2. **Participate in the development of data quality objectives for monitoring activities.**

3. **Review and evaluate internal/external monitoring QA implementation and progress.**

4. **Review and evaluate the quality of data generated by monitoring projects.**

5. **Take corrective action that may be required by audit findings. Corrective action shall be handled at the lowest management level possible. This often should be at the Project Manager's level but if additional resources are needed then the Program Manager should be involved.**

6. **Spot check Project Manager's QA activities.**

7. **Report quality problems to the RQMP.**

8. **Ensuring all staff are aware of the requirements of this policy.**

9. **Ensuring staff comply with this policy and EPA Order 5360.1.**

10. **Requesting appropriate training for staff to comply with this policy.**

D. Regional Project Managers Responsibilities

Regional Project Managers (RPMs) who are responsible for specific monitoring projects, shall be held accountable for the management of the project and its ultimate data products. Therefore, Project Managers have the principal responsibility for ensuring that project data quality objectives are met. Some of the key responsibilities of Project Managers are:

1. Coordinate the preparation of a QA Project Plan for applicable environmental data generation activities and ensure that the QA Project Plan has received an appropriate technical review. Provide the final approval of the QA Project Plan prior to the commencement of data collection. Final approval authority of QA Project Plans resides with the Regional Project Manager. This review will include a review and recommendation on approval or disapproval from the RQMP.

2. Prepare data quality objectives, specifications, and acceptance criteria for the project.

3. Review/evaluate data quality generated from projects.

4. Participate in conducting QA system/performance audits of projects.

5. Approve external (contractor or grantee prepared) QA Program/project plans and submit for RQMP review/concurrence.

6. Review/evaluate data quality generated from external projects.

7. Coordinate project oversight through the use of QA system/performance audits of project QA activities.

8. Take corrective action that may be required by audit findings.

9. Report QM/QA problems to the RQMP.

5.4 Records Management of QM/QA Documents

Official file copies of approved QM/QA Program Plans, Project Plans, SOPs and applicable Program or Project Specific QM/QA documents related to all environmental monitoring programs within Region 10 shall be maintained by the Regional Program Offices. The establishment and routine use of filing system and security procedures are the resposibility of the Regional Program Offices. Applicable QM/QA guidance, requirements documents and agency orders pertaining to QM/QA activities will be maintained and distributed by the RQMP. The RQMP (through the Customer Service Office or CSO) also tracks and maintains documents related to the status of environmental data collection projects that are scheduled through the CSO. In addition, the RQMP maintains Regional copies of technical Statements of Work, Users

Guides and Validation Procedures relevant to Superfunds Contract Laboratory Program (CLP) through the CLP techical project officer (TPO).

5.5 Computer Hardware and Software

The Region 10 Senior Information Resources Management Official SIRMO), located within the Office of Management, is responsible for managing the hardware, software, and communications components for the Region in accordance with Agency hardware and software standards. In conjunction with this effort, the SIRMO has developed and adopted the following guidance and policies for Region 10 (attached as Appendix G).

- Region 10 Security Policy
- Region 10 Electronic File Management Guidance
- Guidelines and Protocol for sending, receiving and using Electronic Information

5.6 Communication/Reporting/Work Plan

The purpose of communications is to ensure that staff personnel in different monitoring programs can effectively develop and implement programs; perform activities; and resolve problems. One responsibility, of the QM Program, is to facilitate communications through the establishment of guidance documents and the issuance of procedures. QAMS shall be considered, by the Region, as the Agency's environmental monitoring QM/QA clearinghouse. As such, all QM/QA items of interest or need to the Region, shall be provided by QAMS to the RQMP. Regional needs shall be forwarded, by the RQMP, to QAMS for review and action. The RQMP shall exchange QM/QA information with the QM Managers of: NERL's, EPA Laboratories, and Head-quarters' Program Offices.

The RQMP shall exchange information with Regional Program Managers, Regional Project Managers, OEA Technical Specialists, and State QA Officers. The State QA Officers shall communicate with appropriate state environmental monitoring personnel, local Agencies' QA Officers, and industrial QA Officers.

By October 1 of each year, the RQMP shall submit a QM Status Report and Work/Audit plan to Regional Management and to the Director of QAMS. This report shall reflect the implementation status of the Region 10 QM Program. The Work Plan shall describe

all planned QM activities for the fiscal year beginning in October. The Audit Plan shall describe specific audits and audit responsibilities.

The QM Report/Work Plan shall contain at least the following types of information:

1. **Implementation Status of Regional QM Program.**
2. **Revisions to Regional QM Program Plan.**
3. **Significant QM/QA related needs; i.e., new policies, changes to existing policies, guidance documents, audit protocols, etc.**
4. **Data Quality Objectives.**
5. **Status of QA Program/Projects and Standard Operating Procedures.**
6. **Audits**
7. **Resources**
8. **Training**

In addition to the regular communication/reporting activities described above, the RQMP shall participate in QAMS QM Annual Management/Technical meetings.

5.7 QM Program Operation/Review

Effective management of a data collection program requires periodic assessment of the quality of data being obtained to establish a basis for corrective action, which may be needed. To ensure that this assessment occurs, all environmental monitoring planned or conducted within the Region shall have an associated QA Project Plan, as required by EPA Order 5360.1. The QAPjP must be approved prior to the start of data collection and/or before laboratory arrangements are finalized. The RQMP can assist the programs in the review of the QAPjPs and provide a recommendation on the approval/disapproval of the plans(Figure 2).

Specifically, the QA Project Plan shall ensure that:

1. **The level of needed data quality should be determined and stated before the data collection effort begins.**

2. All environmental data generated and processed shall be of the quality and integrity established by each QA Project Plan.

Oversight of the data generation activities in Region 10 shall be tailored to the nature of the activity and the associated management and administrative system. Within the Region, QA operations and overview fall into three categories: 1) internal (data generation programs designed and operated by Regional EPA staff); 2) grants and cooperative agreements (data generation under program grants, etc.); and 3) contracts and interagency and other formal agreements (special contract studies, USGS, NOAA work, etc.). A brief description of QA operations and review procedures in each of these categories follows:

A. <u>Internal QA Operation (item 1)</u>

Program Managers/Project Managers shall be responsible for preparing, review and approval of QA Project plans prior to data collection. The RQMP will be available to assist in the development of QA Project Plans and shall review and provide a recommendation of their approval/disapproval. The RQMP shall review and evaluate the implementation of selected plans during the operational phase of the monitoring activity. Within resource constraints, selection of projects will depend on the following criteria: projects supporting litigation, high visibility projects, and requests from Project Managers. Upon completion of the monitoring activity, the Program Manager/Project Manager, etc. shall assess the actual performance of the planned activities and subsequent results. The final project report shall contain the results of this assessment.

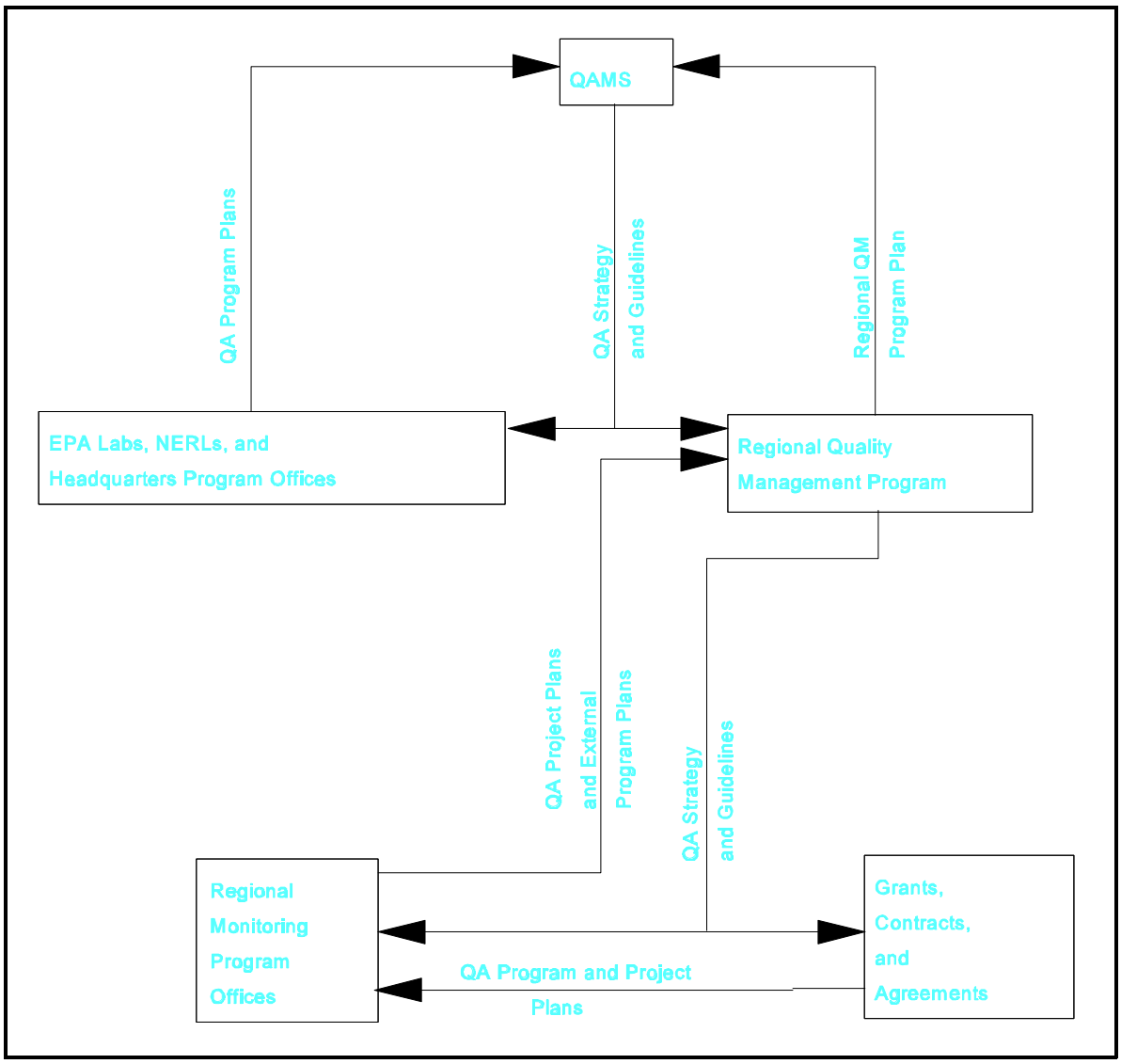


Figure 2. QA Program/Project Plan Preparation, Approval, and Overview. (Approval and Overview occurs in the reverse direction indicated for QAPP submission.)

B. QM Operations for Contracts and Interagency and Formalized Agreements (items 2 and 3)

The originating Program Office shall notify the RQMP of all contracts and interagency/formalized agreements during the planning phase. The RQMP shall ensure that all requests for proposals shall contain an acceptable description of the QA requirements prior to advertisement. The Program Office shall ensure that QA Program/Project Plans are acceptable prior to awarding of the contract or interagency/formalized agreement. QA Program/Project Plans shall be reviewed and approved by the OM Program Manager/Project Manager. The RQMP shall provide assistance in the review of QA Project Plans and provide recommendations on their approval/disapproval. The Program Manager/Project Manager shall review and evaluate the use of these Plans. Upon completion of the monitoring activities, the Program Manager/Project Manager shall assess the actual performance of the planned activity and subsequent results.

The RQMP Manager must review the QA component of all regional contracts, IAGs, SEAs, that involve environmental data collection activities and concur on their approval.

5.8 Program Evaluation

Audits are the principal means in Region 10's QM Program to determine compliance with established QA Program/Project Plans. Different types of audits are used to verify that measurement systems are operating properly; to assess whether data quality information is adequately documented; and to evaluate the management of QA programs. The RQMP has the primary responsibility for conducting audits, and has the authority to delegate certain audit functions to various Technical Specialists within OEA.

The Agency's QM Program requires that an adequate level of auditing be performed in all EPA programs involving the collection of environmental data. Toward this end, Region 10 shall prepare and submit, along with the annual Report, a Regional Audit Program Plan. This Audit plan shall describe the scope, schedule, and types of audits to be conducted in Region 10 during the fiscal year. The choice and type of audit shall be based on applicable regulations, program guidance, emergency requirements, and resource constraints.

Four specific types of audits will be used at appropriate times by Region 10 to determine the status of measurement

systems; the adequacy of the data collection systems; the completeness of documentation of data collection activities; and the abilities of program management to meet mandated data collection and data quality objectives. These four audit types are respectively: performance audits, technical system audits, data quality system audits, and management system audits.

Each type of audit is described below:

1. Performance Audits: Qualitative audits in which data are independently obtained for comparison with routinely obtained data in a measurement system.

2. Technical System Audits: Qualitative audits that shall include, on-site evaluation of the QA system and physical facilities for sampling and analysis.

3. Data System Audits: Quantitative audits in which measurement data are reviewed and evaluated following collection, to determine conformance to data quality objectives and data reduction methods.

4. Management System Audits: Qualitative audits to assess the ability of monitoring program managers to implement and conduct an effective QM/QA program.

A description of specific audits and audit responsibilities shall be presented in the Region 10 QM Audit Program Plan. Audit procedures are described in Appendix E. Without exception, all audits shall be conducted by senior EPA technical specialists; who are familiar with the technical and procedural requirements of field and laboratory operations and applicable sampling QA Project Plans. Non-EPA specialists shall not be used to lead audits.

The results of system and performance audits shall be documented by the auditor(s) for presenting a visual picture of the performance of the program, to see if the minimum requirements of the Agency's QM program are being met. If not, deviations will be identified and recommendations made for corrective action. If corrections are not made, recommendations will be made to the appropriate program manager for action (i.e., withholding grants or contract funds, etc.).

5.9 Resources

Through workload models, Headquarters recommends funding levels for QM activities in each of the monitoring programs. The OEA Director, the RQMP, and the individual program managers

jointly determine the level of resources that need to be allocated to the OEA, to ensure program compliance with QM objectives. Region 10 Program Managers allocate the enabling QM resources to the OEA Director. The OEA Director, in turn, distributes these QM resources within the OEA. Some portion is dedicated to the continuing support of the RQMP, with the balance distributed to the units responsible for providing technical support to the respective programs. The amount and distribution of QM resources, in the Region, is not static, but a dynamic function of the changing emphases of Agency monitoring programs. Therefore, resources allocated to the QM Program, for each fiscal year, shall be explicitly identified in the annual QM work plan.

6.0 CONCEPTS AND CONSIDERATIONS OF QUALITY ASSURANCE PROJECT PLANS

Environmental-related measurement activities include: all field and laboratory investigations which generate data; and the data processing functions which include data storage, retrieval, and analysis. QA Project Plans shall be developed and implemented for all environmental monitoring activities, so that all data generated and processed shall be of acceptable and documented quality.

6.1 Quality Assurance Project Plan Contents

The QA Project Plan (QAPjP) documents the data quality objectives (DQOs) (acceptance criteria) for a project; identifies the critical measurements to be performed; and discusses the QA activities to be conducted during the sampling, analytical, and validation phases of the project. All QA Project Plans shall adhere to QAMS-005/80 (Appendix B); Region 10's Program-Specific QA Project Plan Guidance Manuals (Appendix C); Headquarters' QA Project Plan Guidance Documents (Appendix D); and/or Laboratory QA Plan Guidance (Appendix F). Region 10's QA Manuals are designed to provide explicit guidance for the development of comprehensive Program Specific QA Project Plans. These manuals will aid Program Managers/Project Managers by advising them of quantitative limits of data quality associated with available methodologies. This shall not relieve them of the sometimes difficult task of establishing individual project DQOs. These guidances and the RQMP will assist them, by informing them of data quality limits achievable through the various methodologies.

The QA Project Plan shall contain the following types of information:

1. Title Page, with provision for approval signatures
2. Table of Contents (more than 5 pages)
3. Project Description
4. Project Organization and Responsibilities
5. Objectives for Measurement Data
6. Sampling Procedures
7. Sample Custody and Documentation
8. Calibration Procedures and Frequency; and Preventive Maintenance
9. Analytical Procedures
10. Data Reduction, Validation, and Reporting
11. Internal Quality Control Checks
12. Performance and System Audits
13. Specific Routine Procedures Used to Assess Data Precision, Accuracy, Completeness, Representativeness, and Comparability.
14. Corrective Action
15. Quality Assurance Reports to Management
16. Safety (if applicable)

Region 10 QM policy requires that all Regional monitoring projects must have an approved QA Project Plan prior to data collection and/or before the scheduling of laboratory space. The RQMP shall review all QA Project Plans and concur on approval of final plans. Upon request, the OEA Technical Specialists shall peer review all QA Project Plans within their area of expertise. The QAMS and Headquarters' programs are expected to provide guidance and assistance to the RQMP on the preparation of project plans; either through written documentation, workshops, or on an individual consultation basis.

6.2 Data Quality Objectives

Data Quality Objectives (DQOs) are comprised of qualitative and quantitative statements developed to ensure that data of known and appropriate quality are obtained, to support specific decisions or regulatory actions. Over the years, EPA has refined the primary tool used to derive project specifc DQOs. This is known as the DQO Process. The RQMP encourages the use of the DQO process through EPAs guidance documents: ***Guidance for the Data Quality Objectives Process (Interim Final), EPA QA/G-4, July 1994*** and ***Data Quality Objectives Process for Superfund (Interim Final Guidance), EPA 540-R-93-071, September 1993.*** In short, the DQO process is comprised of the following steps:

- Clarify the study objective
- Define the most appropriate type of data to collect
- Determine the most appropriate conditions from which to collect the data
- Specify tolerable limits on decision error (determining an acceptable level of both false positive and false negative error rates for sample design, collection and analysis) which will be used as the basis for establishing the quantity and quality of data needed to support the decision.

Because the DQO process requires an up-front planning with the project decision makers and stakeholders (e.g., data users, field and laboratory personnel, risk assessors, hydrogeologists, QA specialists, modeling experts, etc..) the OEA has developed an organizationally based project planning process designed to compliment the DQO process for internal Regional use. This document (attached in Appendix G) outlines the: 1) team approach to project planning, 2) roles and responsibilities of team members, 3) the use of scoping meetings, 4) development and implementation of Work Plans and QA Plans, and 5) communication processes between team members and decision makers.

6.3 Laboratory Quality Assurance Plan Contents

The Laboratory QA Plan shall contain the following types of information:

1. Title Page
2. Table of Contents

3. Quality Assurance Policy Statement
4. Corporate Ethics Policy on Waste, Fraud, and Abuse
5. Quality Assurance Management
6. Administrative Organization
7. Personnel Qualifications
8. Facility Description and Capital Equipment
9. Preventive Maintenance
10. Corrective Action
11. Laboratory Evaluation and Audits
12. Quality Assurance Reports to Management
13. Lab Documentation and Forms
14. Sub-Contracting of Services
15. Standard Operating Procedures
16. Laboratory Personnel Training Record

It is highly recommended that a copy of the Laboratory QA Plan be obtained and reviewed, to determine laboratory capabilities and QC procedures, prior to the awarding or arrangement of any laboratory services. The RQMP can provide assistance in reviewing Laboratory QA Plans.

6.4 Standard Operating Procedures

Standard Operating Procedures (SOPS) are documented methods for performing certain routine or repetitive tasks. These tasks frequently involve such operations as sampling, sample tracking, analysis, instrument or method calibrations, preventive and corrective maintenance, internal quality control, and data reduction and analysis. The SOPs shall be prepared in document control format by the user, as required, and shall be maintained on permanent file by the SOP user and the RQMP. The following are considerations involved in the development and utilization of Standard Operating Procedures.

A. Standard Operating Procedures Objectives

1. Adequate to establish traceability to standards, instrumentation, samples, and environmental data.
2. Simple, so a user with basic education, experience, and/or training can properly use them.
3. Complete enough so the user/reader can follow the directions in a step-wise manner through the sampling, analysis, and data-handling processes.
4. Consistent with sound scientific/engineering principles.
5. Consistent with current EPA regulations and guidelines.
6. Consistent with the instrument manufacturers' specific instruction manuals.

B. Benefits of Standard Operating Procedures

1. Record the performance of all tasks and their results.
2. Explain the cause for missing data.
3. Demonstrate the validation of data each time they are recorded, calculated, or transcribed.

C. Items to be Addressed in Standard Operating Procedures

1. General network design.
2. Specific sampling-site selection.
3. Sampling and analytical methodology.
4. Probes, collection devices, storage containers, and sample additives, such as preservatives.
5. Special precautions, such as holding times and protection from heat, light, reactivity, and combustibility.
6. Federal reference, equivalent, and alternate test procedures.
7. Instrumentation selection and use.

8. Calibration and standardization.

9. Preventive and remedial maintenance.

10. Duplicate, spiked, blank samples and analysis.

11. Quality control procedures such as inter-, and intra-field laboratory activities.

12. Documentation, sample custody, transportation, and handling procedures.

13. Safety.

14. Data handling and assessment procedures.

15. Precision, accuracy, completeness, representativeness, and comparability.

16. Service contracts.

17. Document control.

All environmental monitoring shall meet established EPA regulations and guidelines and Region 10 SOPs. Deviations shall be justified and documented. The degree of adherence to the approved SOPs shall be determined during the systems audits. SOPs shall be revised by the user and approved by the user's supervisor. As appropriate, these SOPs may be reviewed by the RQMP.

Agency contractors shall be responsible for developing appropriate SOPs for repetitive work they perform for the Agency. Agency contractors shall be responsible for the quality of their work when using their SOPs. These SOPs, if appropriately written can be used to supplement a QA Plan, but SOPs cannot be used in lieu of an approved QA Plan.

6.5 Data Processing and Verification

Data processing includes collection, validation, storage, transfers, and reduction. Precautions shall be taken each time the data are reduced, recorded, calculated, and transcribed to prevent the introduction of errors and the loss of information.

As our reliance on computers increases, consideration should be given to the transmittal and storage of data in an electronic

(digital) format. Most data systems and users have specific electronic data format requirements. Because of this variability, electronic transmittal and storage of dat will have to be addressed on a project or program specific basis, which is beyond the scope of this document.

The data processing requirements are detailed as follows:

A. Collection - Each QA Project Plan shall address the checks which must be used to avoid errors in the data collection process.

B. Validation - Data validation is defined as, "the process by which data are accepted or rejected based on a set of criteria." Since this aspect of QA may include various forms of manual or computerized checks, criteria for data validation shall be specified in each QA Project Plan.

C. Storage - Each QA Project Plan shall indicate how specific types of data will be stored.

D. Transfers - Each QA Project Plan shall describe procedures which will be used to ensure that data transfers are error-free, and that no information is lost in the transfer. Data transfer steps contained in each QA Project Plan shall be kept to a minimum.

E. Reduction - Each QA Project Plan shall contain procedures for ensuring the correctness of data reduction processes. Data reduction includes, all processes which change either the form of expression or quantity of data items. It is distinct from data transfer in that it entails a reduction in the size (or dimensionality) of the data set. The QA Project Plan must identify the processes used to obtain the reduced data set.

Each QA Project Plan shall describe procedures for verifying the accuracy of the data reduction process.

6.6 Data Quality Assessment

The quality of all environmental data generated and processed shall be assessed for: accuracy, precision, completeness, comparability and representativeness, based upon the QA Project Plans. The data assessment requirements are detailed as follows:

A. Accuracy

Each QA Project Plan shall contain a mechanism which will demonstrate that the reported data are favorably comparable to the true value(s). Examples of activities to assess accuracy are:

1. **Traceability of Instrumentation - Each measurement device shall be assigned a unique identification number. Documentation shall identify the specific measurement device; where and when used; maintenance performed; and the equipment and standards used for calibration.**

2. **Traceability of Standards - Each standard and each measurement device shall be compared against a standard of known and higher accuracy (where possible). All calibration standards shall be traceable to available National Institute of Standards and Technology (NIST). If NIST standards are not available, other documented primary standards shall be used.**

3. **Traceability of Samples - Each sample shall be assigned a unique identification number (laboratory No.). Documentation should identify sampling time, place, samplers name and action taken on each sample.**

4. **Traceability of Data - Data shall be documented to allow complete reconstruction, from initial field records through data storage system retrieval.**

5. **Methodology - If available, Federal reference, equivalent, or approved alternate test methods of known accuracy shall be used. For very critical work, it is recommended, in Region 10 at least, that two independent analytical methods be used to check for accuracy.**

6. **Reference or Spiked Samples - Recoveries shall be within predetermined acceptance limits.**

7. **Performance Evaluation - Each environmental monitoring program shall continually participate in the EPA National and Regional Performance Evaluation Programs.**

B. Precision

Each QA Project Plan shall contain a mechanism which will demonstrate the reproducibility of the measurement process.

Examples of activities to assess precision are:

1. **Replicate Samples - Replicate sample data shall be within predetermined acceptance limits.**

2. **Collocated Samples - Sample data from collocated sampling points or monitors shall be within predetermined acceptance limits.**

3. **Inter-/Intra-Laboratory Testing - Sample data from independent studies shall be within predetermined acceptance limits.**

4. **Instrumental Checks - Each measurement device shall have routine checks performed to demonstrate that variables are within predetermined limits. Examples of these include:**

- **♦ Zero and span**
- **♦ Flow rate**
- **♦ Noise levels**
- **♦ Pressure rate**
- **♦ Drift**
- **♦ Linearity**

C. Completeness

Each QA Project Plan shall identify the quantity of data needed to support a planning or enforcement action. Completeness shall take into consideration the potential for environmental change with respect to time and timing.

D. Comparability

Each QA project plan shall contain procedures to assure the comparability of data. Examples are:

1. **Consistency of reporting units.**

2. **Standardized siting, sampling, and analysis.**

3. **Standardized data format.**

E. Representativeness

Each QA Project Plan shall contain procedures to ensure that all samples collected, are as accurate and precise as possible and represent the media sampled.

Examples of activities to assess representativeness are:

1. Site Purpose - Each sampling site shall have a preidentified and documented purpose.

2. Site Description - Each sampling site shall be specifically identified by location and by suitability to meet the pre-identified purpose.

3. Site Photo Documentation - Each sampling site should be photographed from each of the four major compass directions when possible.

4. Sampling Conditions - The conditions under which each sample was collected shall be described. Conditions include such items as:

   - ♦ Stream flow and homogeneity
   - ♦ Temperature
   - ♦ Wind speed and direction
   - ♦ Barometric pressure

6.7 Corrective Action

Each QA Project Plan shall include, provisions for written requirements establishing and maintaining QM reporting or feedback channels to the management responsible, to ensure that early and effective corrective action can be taken when data quality falls outside established data quality objectives (acceptance criteria). Each QA Project Plan shall also include, provisions to keep responsible management informed of the performance of all data collection systems. Each QA Project Plan shall describe the mechanism(s) to be used when corrective actions are necessary. Corrective action shall relate to the overall QA management scheme: who is responsible for taking corrective actions; when are corrective actions to be taken; and who follows-up to see that corrective actions have been taken and that they have produced the desired results?

7.0 TRAINING

Each monitoring program manager shall ensure that all personnel performing tasks and functions related to data quality shall have the needed education, training, and experience. This includes laboratory technicians, analysts, maintenance technicians, supervisors, principal investigators, statisticians, project managers, and Regional QM staff. Training needs shall be identified during performance evaluations and through career

development plans. The RQMP develops and provides QM/QA guidance manuals and identifies QM/QA training courses. Training needs are not static, but are a dynamic function of program requirements. Therefore, training needs shall be addressed in the Region's Annual QM Report/Work Plan. The Report/ Work Plan shall be submitted annually to the Director of QAMS for approval.

8.0 IMPLEMENTATION REQUIREMENTS AND SCHEDULE

Implementation of the Agency's mandatory QM Program requires that each major milestone be identified and scheduled for accomplishment. Major National/Regional milestones shall be identified, scheduled, and progress reported in the Region's Annual QM Report/Work Plan. The Report/Work Plan shall be submitted annually to the Director of QAMS for approval.

APPENDIX A - EPA Order 5360.1 Mandatory Quality Assurance

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 17 1984

Office of
The Administrator

Memorandum

SUBJECT: EPA Order 5360.1, "Policy and Program Requirements to Implement the Quality Assurance Program"

FROM: Alvin L. Alm
Deputy Administrator

TO: Addressees

One of my major goals is to ensure that all decisions by EPA can be supported by a sound data base. An important step toward achieving this objective is to require that quality assurance become an integral part of all data collection activities. Quality assurance is the total integrated program for assuring the reliability of environmental measurements and consists of multiple steps undertaken to ensure that all acquired data are suitable for the user's intended purpose. Two of the major steps are: the user must first specify the quality of data he needs; then the degree of quality control necessary to assure that the resultant data satisfies his specifications must be determined. Central to this process is assuring that the data is of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible.

In order to establish quality assurance solidly in all data collection activities, the important step of issuing this order on quality assurance is being taken. The implementation of the elements in this order will require dedication and hard work by the Quality Assurance Management and Special Studies Staff, by quality assurance officers throughout the Agency, and by senior management. This order identifies the goals, objectives, and general responsibilities of each program area. To carry out the order, specific policy and technical guidance materials need to be prepared. I will be following that progress.

The attached order reflects my commitment to the Agency's QA program and to the promotion of good science in all EPA monitoring and measurement activities. Therefore, I expect that each of you work cooperatively to ensure that the appropriate level of quality assurance is embedded in all data collection

undertaken by or for the Agency.

POLICY AND PROGRAM REQUIREMENTS TO IMPLEMENT THE MANDATORY QUALITY ASSURANCE PROGRAM

1. PURPOSE. This Order establishes policy and program requirements for the conduct of quality assurance (QA) for all environmentally related measurements performed by or for this Agency.

2. BACKGROUND. Agency policy requires participation in a centrally managed QA program by all EPA organizational units supporting environmentally related measurements. Under Delegation of Authority 1-41, "Mandatory Quality Assurance Program" (dated 4/1/81), the Office of Research and Development (ORD) is the focal point in the Agency for quality assurance policy and is responsible for developing QA requirements and overseeing Agencywide implementation of the QA program. ORD established the Quality Assurance Management and Special Studies Staff (QAMSS) to serve as the central management authority for this program. The QAMSS activities involve the development of policies and procedures; coordination for and direction of the implementation of the Agency QA program; and review, evaluation, and audit of program activities involving environmental monitoring and other types of data generation.

   The Agency QA program embraces many functions including: establishing QA policy and guidelines for development of program and project operational plans; establishing criteria and guidelines for assessing data quality; serving as a QA information focal point; auditing to ascertain effectiveness of QA implementation; and identifying and developing QA training programs.

3. GOALS AND POLICY. The primary goal of the QA program is to ensure that all environmentally related measurements supported by the EPA produce data of known quality. The quality of data is known when all components associated with its derivation are thoroughly documented, such documentation being verifiable and defensible. It shall be the policy of all EPA organizational units to ensure that data representing environmentally related measurements are of known quality. Decisions by management rest on the quality of environmental data; therefore, program managers shall be responsible for: 1) specifying the quality of the data

required from environmentally related measurements and 2) providing sufficient resources to assure that an adequate level of QA is performed. All routine or planned projects or tasks involving environmentally related measurements shall be undertaken with an adequate QA project plan that specifies data quality goals acceptable to the data user and assigns responsibility for achieving these goals.

In discharging its responsibility for implementing the Agency-Mandated Quality Assurance Program, the ORD/QAMSS will strive for consensus by submitting for review proposed policies and procedures to affected program offices and regions. Responsibility for adjudication of unresolved issues, with respect to the above and QAMSS conducted audits, will be at the lowest level of authority consistent with the scope of the issues. The QAMSS will refer issues which remain unresolved at lower levels of authority to the AA/ORD for decision, after consultation with the appropriate AA or RA.

The following activities are basic to the implementation of the QA program:

a. Preparation and annual update of a QA program plan based on guidelines established by QAMSS.

b. Developement of a QA project plan for all projects and tasks involving environmentally reelated meaurements in accordance with guidelines established by QAMSS.

c. Assuring implementation of QA for all contracts and financial assistance involving environmentally realted measurements, as specified in applicable EPA regualtions, including subcontracts and subagreements.

d. Conducting audits (system, performance evaluations, data quality, bench, etc.) on a scheduled basis of organizational units and projects involving environ-mentally related measurements.

e. Developing and adopting technical guidelines for estimating data quality in terms of precision (variability), bias (accuracy), representativeness, completeness and comparability, as appropriate, and incorporating data quality requirements in all projects and tasks involving environmentally related

(7) Serve as the Agency QA information focal point.

(8) Develop generic training program, based on perceived needs, for all levels of management to assure that QA responsibilities and requirements are understood at every stage of project implementation.

(9) Ensure that all ORD investigations involving data collection are covered by an acceptable QA plan with resources adequate to accomplish program objectives.

(10) Ensure that deficiencies highlighted in review of ORD program plans or in audits of ORD components are appropriately addressed.

b. In accordance with policies and procedures established by AA/ORD, National Program Managers shall:

(1) Ensure that QA is an identifiable activity with associated resources adequate to accomplish program goals in the development and execution of all projects and tasks, both intramural and extramural, involving environmentally related measurements.

(2) Ensure that appropriate QA criteria are included in operating guidance.

(3) Establish data quality acceptance criteria for all projects and tasks conducted by the program office.

(4) Ensure that an adequate degree of auditing is performed to determine compliance with QA requirements.

(5) Ensure that deficiencies highlighted in audits are appropriately addressed.

(6) Ensure that all projects and tasks involving environmentally related measurements are covered by an acceptable CA project plan and that the plan is implemented.

(7) Identify program-specific QA training needs and provide for the required QA training.

C. In accordance with policies and procedures established by AA/ORD, Regional Administrators shall:

measurements.

f. Establishing achievable data quality limits for methods cited in regulations based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77.

g. Implementation of corrective actions, based on audit results, and for incorporating this process into the management accountability system.

h. Provision for appropriate training based on perceived needs, for all levels of QA management, to assure that QA responsibilities and requirements are understood at every stage of project implementation.

4. RESPONSIBILITIES.

a. In conformity with the oversight responsibility for the mandatory QA program, the AA/ORD shall:

(1) Establish Agency policies and procedures for implementing the mandatory QA program.

(2) Provide guidance for determining precision, bias, representativeness, completeness, and comparability of data.

(3) Review QA Program Plans from Agency components involved in environmentally related measurements.

(4) Conduct QA audits of all organizational units supporting environmentally related measurements based on established audit criteria and procedures.

(5) Recommend corrective actions, based on audit results, for inclusion in the management accountability system.

(6) Establish achievable data quality limits for methods provided by ORD for citation in regulations, based on results of methods evaluations arising from the methods standardization process, e.g., ASTM Standard D2777-77, to help project officers define data quality goals.

(c) Environmentally Related Measurement. Any laboratory or field data gathering activity or investigation involving the determination of chemical, physical, or biological factors related to the environment.

The following are representative examples of environmentally related measurements. Data collection or investigation of chemical, physical, or biological factors for determination of:

(1) pollutant concentrations from sources, in the ambient environment, or pollutant transport and fate;

(2) response of organisms to pollutants;

(3) the effects of pollutants on human health and on the environment;

(4) risk/benefit analysis;

(5) environmental or economic impact.

(6) the environmental impact of cultural and natural processes;

(7) pollutant levels, exposure levels, etc., used in modeling.

(d) Organizational Unit. Any administrative entity (national program office, regional office, ORD or NEIC laboratory) which engages in environmentally related measurements.

(e) Project. An organized undertaking or specified unit of investigation involving environmentally related measurements.

(f) Quality Assurance. The total integrated program for assuring the reliability of semitoring and measurement data.

(g) Verifiable. The ability to prove or substantiate any claim or result related to the documented record.

6. ADDITIONAL REFERENCE. This Order will be amplified by a detailed implemetation plan.

EPA ORDER

5360.1
APR 3 1984

Howard M. Messner
Assistant Administrator
Office of Administration and
Resources Management

APPENDIX B - Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans

APPENDIX C - Regional Program-Specific Quality Assurance Project Plan Guidance Manuals

APPENDIX D - Headquarters Program-Specific Quality Assurance Project Plan Guidance Documents

APPENDIX E - National/Regional Audit Procedures

APPENDIX F - Laboratory Quality Assurance Plan Guidance Documents

APPENDIX G - Related Regional Program-Specific Documents

PROJECT PLANNING - A PROCESS

BACKGROUND

The Off ice of Environmental Assessment (OEA) has a powerful array of technical experts in the areas of quality assurance, laboratory analysis, ecological and health risk assessments, field monitoring, modeling, facility inspections, engineering data management, GIS applications, economics and data interpretation.

The OEA Management Team recently conducted a review of OEA's organization effectiveness in an effort to identify impediments to the overall effectiveness of the office. These included: 1) the need f or a strategic - planning process; 2) early and continued involvement of key technical and management personnel in project planning; 3) confusion over roles and responsibilities and 4) lack of a clear decision-making process.

The balance of this document addresses the project planning issue and roles and responsibilities associated with project planning. While strategic planning will be addressed in a separate document, it should be noted that an effective strategic planning process will play an important role in addressing project planning issues. Attached is a simplified flow diagram depicting a potential project planning process.

PROJECT PLANNING

Team Approach - The new regional organization disperses responsibility for the Region's programs across several offices, many without a single, media focus. Successful project managers will assemble teams of relevant expertise from all affected off ices. Team members may be more or less active at various stages of the project but should remain informed and involved. The team approach is characterized by frequent communications between team members and frequent meetings of the team and any designated subsets. In addition to insuring that the project remains focussed, frequent interaction between team members insures that roles and responsibilities remain clear.

Decision-making - Historically, one of the major conflicts between ESD (and to a lesser degree ORC) and some program offices centered on the way and degree science and legal input was used by the program in the project planning and decision making processes. That the program should make programmatic decisions has never been in dispute, only the process by which the relevant factors, specifically science and legal considerations, have been factored into the project planning and decision making process. The team approach will go a long way toward involving relevant expertise and defining issues and options. However, successful project planning will also require a clear decision-making process with a recognized mechanism for resolving disputes.

ROLES AND RESPONSIBILITIES

Successful teams are those which function in a setting characterized by honesty, respect and candor. Everyone's views are encouraged, solicited, and honored. The only agenda pursued by team members is the project. Above all, the successful team communicates often and well.

Roles by Function

Team Leader - The team leader has a major leadership role in the conduct of the business of the team. The team leader would most often be the program representative initiating the project. This person would be responsible for initially deciding the general composition of the team and calling the first meeting. The team leader would evaluate team exchanges to insure that team rules were followed. This individual also has particular responsibility for keeping team members well informed throughout the life of the project.

Team Members - Each team member has the responsibility to insure that team rules are followed. They have the obligation to participate and be interested throughout the life of the project. Team members must understand how their work fits into the overall project and be committed to its success. They must avoid programmatic or discipline parochialism and work for the result that best protects the public interest.

Roles by Discipline

Program Representative(s) - Program representatives will bring to the team the program requirements for the project. These will be extremely important since the project will have often been initiated by the program to accomplish a program goal. The program representatives will help the team understand the scope and objectives of the project and any potentially confounding implications such as resources, politics, policy, or public concern.

Science Representative(s) - Science representatives may come from several different organizations depending on the needed discipline. The scientists' responsibility is to provide objective and relevant scientific input into all phases of the project planning and execution processes. The scientists will be expected to take a primary role in determining data needs, evaluating data quality and assist the team in understanding the application of the data to the project parameters.

Legal Representative(s) - Attorney support may be necessary to insure that any action consequent to the project is legally defensible. The legal representative should be an active participant in project deliberations since intimate knowledge of the project might result in an innovative legal interpretation that yields better project decisions.

Role of the Contractor The availability of contractors provides options in assigning work, an especially attractive option given the lack of growth in the federal work force. Irrespective of their use, the team must rely heavily on relevant EPA staff to insure appropriate oversight of contractor work. The level of oversight required will he decided on many factors, such as

contractor experience, chances of litigation, and resource limitations. In many cases, contractors prepare work plans and QA project plans.

PROJECT PLANNING FOR EFFECTIVE DECISION-MAKING

What follows is an outline of a potential project planning process.

- **Scoping Meeting** - The scoping meeting is a critical step in the project, planning process. Once the project officer concludes a project approach is appropriate and that the resource investment will be consistent with Regional priorities, a scoping meeting is called. The project officer must be well prepared for this meeting. He/she must insure that the right people are present and clearly define the scope and objectives of the project. The discussion should clarify the objectives where there is some uncertainty or where the expertise represented at the meeting describes a better objective or a more appropriate scope. The participants may suggest including additional expertise in the meeting to better accomplish project goals.

- **Work Plan**-- The work plan is prepared which describes the work to be done, the schedule for its accomplishment and who is responsible for the various elements. For some projects, a Statement of Work (SOW) is prepared for work the contractor is expected to perform. In both cases, while the author might be the team leader, the team should be involved in the definition of the major elements of the document. Differences of opinion regarding the data needs for the project must be resolved before finalizing the work/QA plan. The project sponsor (probably the team leader) requesting the project will make a decision on data needs where consensus cannot be reached. Their decision can be appealed to the decision maker if the person disagreeing with the decision feels the project would be compromised.

- **Work/QA Plan Implementation** - When the work/QA plan is endorsed by the team and finalized, the various processes by which work is accomplished must be activated. Naturally, the earlier a work process is accessed, the more responsive it can be. For projects profiting from the science/technical expertise OEA has to offer, for-example, the work would be requested through OEA's project/tracking system. This system keys off the Work/QA plan but reduces the project focus to OEA scale providing a detailing of the scientific/technical expertise required, a sense of the scope of work expected of OEA, its relative priority, and deadlines. The same tracking system would pertain whether OEA was doing the work or reviewing the work of the programs and/or contractors.

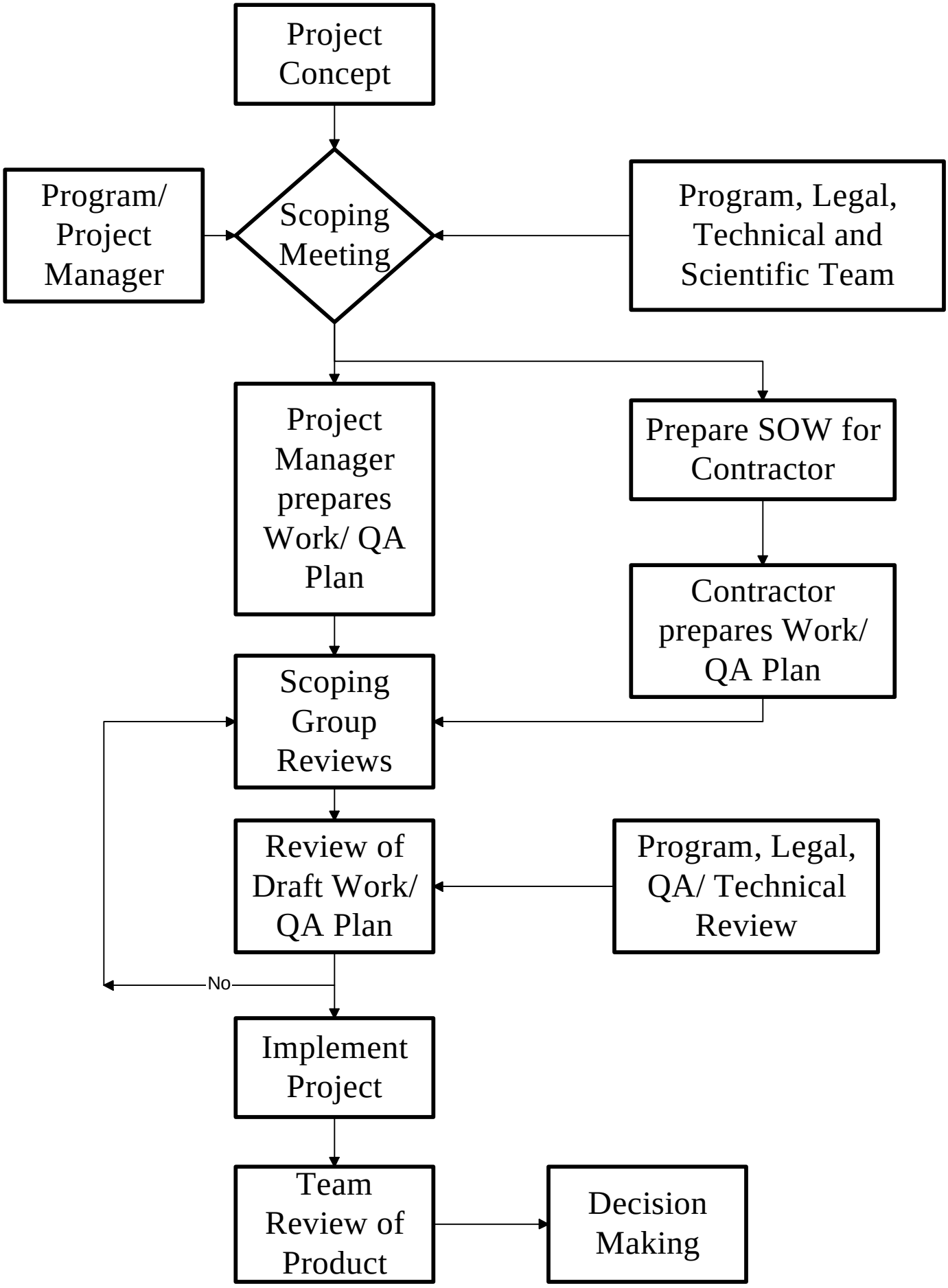
- **Decision - making** - When the relevant information has been collected, the team would meet to discuss the project in the context of the Regional priority that defined the projects need. At this point, any differences of opinion between team members would be explored in detail and hopefully resolved by consensus. The team leader would then forward the

team's recommendation to the decision-maker. If consensus cannot be reached, the team leader would forward a recommendation to the decision-maker with a accurate representation of any substantive disagreements. The decision-maker would evaluate the recommendation and any outstanding disagreements. The decision-maker may wish to call a meeting of the team to discuss the recommendation and any outstanding issues. In any case, if a member of the team disagrees with the recommendation, they can meet with the decision-maker to discuss their disagreement before the final decision is made. Once the final decision is made the team is notified of the decision and its basis.

- **Communication** - Good communication is the responsibility of all team members. If any team member feels that responsibilities and expectations are-not defined well enough, he/she should address that issue first with the team leader and/or the entire team. Similarly, if the basis for a decision is not communicated clearly to any team member, that individual should take the initiative to seek out the team leader and/or decision-maker, if needed.

CONCLUSION

The Region is blessed with a remarkable array of talent. Too often, this powerful capability is neutralized by our failure to apply it effectively. A process that effectively mobilizes the right people and engages them in an honest and considerate fashion will substantially improve the quality of many of the Region's more difficult decisions.


Project Concept
Program/ Project Manager
Scoping Meeting
Program, Legal, Technical and Scientific Team
Project Manager prepares Work/ QA Plan
Prepare SOW for Contractor
Contractor prepares Work/ QA Plan
Scoping Group Reviews
Review of Draft Work/ QA Plan
Program, Legal, QA/ Technical Review
No
Implement Project
Team Review of Product
Decision Making

REGION 10 COMPUTER SECURITY POLICY

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APPENDICES

I. Overview: Importance of Computer Security

Region 10 has made a significant investment in the information we store on our personal computers, local area networks (LANs) and the mainframe computer in the National Computer Center (NCC), Research Triangle Park, North Carolina. We have spent millions of dollars on our computer hardware in order to establish the computing environment which exists today and which we have grown to depend upon to perform our jobs. The responsibility to protect these investments rests with the users of the computers. This policy document has been prepared to:

a) Describe both regional and national security measures that need to be taken to ensure the basic physical protection of personal computers (PCs), LAN workstations, mainframe terminals, and the magnetic media upon which all of our valuable information is stored, and

b) Set forth administrative procedures governing the use of our computers and software.

The "EPA Information Security" and "EPA Information Security for Personal Computers" manuals give more detailed information about

Agency-wide policy on computer security. Section 2.3 in both manuals specifically addresses implementation of minimal controls for information security; specifically, information sensitivity determination and risk analysis requirements are discussed.

All security policies and procedures established by this document also apply to work carried out at home or while in travel status.

If you wish to examine a copy of these manuals, please contact the Chief, Information Technology Section at X2988.

II. Physical and Environmental Controls

The following controls for PCs, LAN workstations and mainframe terminals are required to prevent theft and physical damage:

- Locate PCs away from heavily travelled and easily accessible areas to the extent possible, on stable desk tops.

- PCs and LAN workstations should not be plugged directly into the wall; surge protection devices have been provided to protect our computers against surges in current. It is mandatory that these devices are used. If a PC is missing a surge protector, contact the PC Hotline immediately. A new unit will be supplied from stock.

- Physical configuration of equipment must not be modified by the user. The PC Hotline should be requested to make any required moves of equipment. Requests should be directed by WPO message to PCHOTLINE or alternatively by phone to X1201. The Information Management Branch (IMB) also tracks all

changes in the Region 10 computer inventory system which contains up-to-date information about each PC and LAN workstation configuration owned by the region. It is essential that this information be kept current at all times.

- Computer equipment should not be installed in direct sunlight or in locations with extreme temperatures (less than 50 degrees Fahrenheit or greater than 100 degrees Fahrenheit).

- Computer equipment and magnetic storage media are sensitive to contamination from dirt, smoke, or magnetic fields. Do not eat or drink in the immediate vicinity of the computer.

- Portable PCs require additional security considerations because they are more vulnerable to theft. Portables should be stored in locked cabinets when not in use. The person named on the Sensitive Item Registration card is responsible for the portable computer and must keep a log to track loans of these units by the person who signed the registration card.

- Manuals are to be labeled with the user's PC Configuration number and kept near the PC to facilitate reference.

The following additional security control will be extended to the LAN servers and other equipment located in the computer room.

- Access to the computer room will be strictly controlled. The door to the computer room is to remain locked at all times. Only those persons whose names appear on the authorized access list are to be permitted unaccompanied access. Repair persons, people from headquarters, etc. are to be logged in and out. The log entry must specifically identify the reason for the visit.

III. Software Copyrights/Licenses and Master Copies

- Most personal computers with hard disks in Region 10 have Lotus 1-2-3, dBase and WordPerfect installed as the standard agency software. LAN and mainframe computers also have standard agency software installed. In addition, EPA has purchased copies of software on a case-by-case basis to perform specific functions such as project tracking and graphics.

When we buy software, we are purchasing a license agreement with the manufacturer whereby we are prohibited from duplicating either the software or documentation. In general, there are two types of software licenses: single-machine and site. A single- machine license allows the user to install the master copy of the software on his/her PC only. With a site license, the software may be installed on more than one PC or a LAN file server, typically for a higher fee. Copying single-machine software, therefore, for use on another computer is a violation of the license agreement. Making copies of software for personal use not only violates copyright laws, but is a theft of government property. Using unauthorized copies of software on EPA computers is also illegal, even if such copies are obtained from sources outside EPA. Willful violations of U.S. copyright law may result in potential for personal liability.

- EPA purchased software shall be used exclusively on EPA owned computers (except when permitted by the licensing agreement, eg. WordPerfect). EPA software should not be installed on PCs owned by contractors without written approval of IMB.

- All master copies of software purchased by EPA (including purchases made by Headquarters) for use in Region 10 must be sent to the Information Management Branch, where the diskettes will be stored in a locked room to ensure accountability and control. This is required for security purposes as well as to facilitate regionwide software upgrades. Software vendors require that we either destroy or return the master diskettes for each copy of the software that is to be upgraded.

- Software purchased by contractors and used in support of specific EPA related contract activities is subject to the same approval requirements as software purchased by EPA. Master copies of the software must also be sent to the IMB for storage. Project Officers for all EPA contracts are responsible for being knowledgeable of all contractual requirements regulating the contractors' use of computer hardware and software for EPA business. Questions regarding such requirements should be directed to the contracting official.

IMB will conduct unannounced, random audits of Region 10 computers; should illegal or unauthorized software be located on an employee's computer, appropriate disciplinary action may be warranted. For additional information on IMB controls, see Section XII, Region 10 Computer Monitoring Procedures on page 9.

IV. Unauthorized use of Computers

Computers have been made available by EPA for use by its employees in the conduct of EPA business. Use of these computers is not allowed for personal business of any kind, even if it is done on the employee's own time. Training and practice on EPA computers shall be done using work related examples and such activities shall be directed towards developing skills to be used to perform job related tasks.

PC games and other non-work related software are strictly prohibited from being installed and/or executed on EPA computers.

V. Non-EPA Software Product Controls

- EPA employees shall not install any software without the approval of IMB. Contracts have been established by OIRM to obtain computer software which are based upon a thorough requirements analysis and are consistent with the Agency's long-term strategic plans. Software standards are issued by the director of the National Data Processing Division (NDPD) after consultation and concurrence by the Director of the Office of Information Resources Management. Software products other than those offered on Agency contracts are generally not permitted on Region 10 PCs. There may be an exception in which an application has specific requirements that are not met by Agency standard software. In this case, a request for use of non-standard software must be submitted to the Information Management Branch for approval. Agency resources are best spent on compatible software which has

been tested prior to delivery and for which user support has been committed. Organizations which acquire non-standard software should be aware of their inherent and potential liability caused by not being part of the Agency's standard architecture.

- Privately-owned commercial software shall not be installed on an Agency computer without prior written authorization from IMB. The request must certify that no license agreement will be violated, the software will be properly segregated from EPA software, and agency (sensitive) data will not be stored in non-standard format through use of this privately-owned software. The user will be required to produce the license for this software upon request.

  Use of database software other than CLIPPER and dBASE III+/IV, for EPA multi-user system development is not permitted. Privately-owned database software is also strongly discouraged in the development of single-user systems (i.e. a personal project tracking system).

- Public domain software exists and is not subject to any license agreement/copyright laws. However, public domain software used on EPA computers must be used only in the performance of job related functions.

  IMB written approval and virus-scanning are required before any public domain software can be loaded on an agency computer.

VI. Computer Viruses

A computer virus is an extra program hidden within an apparently normal program or software package referred to as the virus "host" or "Trojan Horse". Like a biological virus, the computer virus has two important characteristics: it can replicate itself and it can cause harm or mischief. This replicating ability means that a virus can quickly spread via shared diskettes, networks, electronic bulletin boards, or file servers as programs or files are stored, executed, uploaded or downloaded. Potentially infected host software include any of our standard software packages. Truly malicious viruses can modify or destroy programs and data.

To detect and combat viruses, a number of specialized programs or software "vaccines" have been developed. However, it is not possible to develop a set of generic procedures to ensure the integrity of non-EPA computer products, public domain software, EPA application software and data diskettes.

- Failure to detect viruses may result in destruction of government property (software and data). Due to the serious nature of software viruses and the severe damage that can occur, all disks that originate outside of Region 10, EPA must be scanned by virus detection software prior to installation or use on any EPA computer. Bring disks to be scanned to the PC Hotline Help desk on the 8th floor or to the Computer Room on the 10th floor. In addition, both places can provide you with virus scanning disks which can be used to check any IBM compatible PC for viruses. It is permissible to use these virus check disks at home. If a virus is detected, the user's PC will display a message alerting the user that a virus has been found; the user should contact the PC Hotline immediately - DO NOT ATTEMPT

TO REMOVE THE VIRUS YOURSELF. PC Hotline will dispatch PC specialists who will remove the virus and take all precautionary measures necessary to prevent the virus from infiltrating the LAN. All Region 10 Servers are scanned for viruses on a daily basis.

- EPA employees and contractors who use PCs or LANs are also subject to the virus prevention policies set forth in the National Data Processing Division (NDPD) Operational Policies Manual, regarding installation of new software, backups and virus-scanning requirements. A copy of this manual is held by Chief, Information Technology Section.

VII. Magnetic Media (Information Storage) Controls

Virtually all information on computers in Region 10 is stored on magnetic media in the following forms:

- Diskettes
- Fixed disks (hard disks) inside the PC
- Large capacity fixed disks inside the LAN file servers
- Cartridge tapes
- Removable disk cartridges (Bernoulli cartridges)
- Mainframe disk storage (DASD)

Computer users need to treat magnetic media with special care. Flexible diskettes are especially susceptible to damage.

- Keep disks away from magnetic fields, such as radios, TVs or microwave ovens.

- Do not bend diskettes.

- Store disks in a storage box when not in use.

- 5.25" disks need extra care. Do not: touch the exposed media, write on them with hard tipped pens, or store them without their dust jackets.

- Contact the PC Hotline for assistance in relocating computers. Do not attempt to move the equipment yourself.

All information that is accessed by more than one user should be stored on the LAN or mainframe depending on the application. Confidential files must not be stored on the Region 10 LAN servers or on single user PCs unless specifically approved in writing by the Director, OIRM. Such data must be stored on diskettes which can be locked up in order to afford the data proper security. Sensitive information can be stored on the IBM 3090 mainframe (and must be secured via the RACF mainframe security facility - contact the PC Hotline to identify the current Region 10 RACF contact. Other types of information can be stored on the PC local hard drive, if one exists, or on floppy diskettes.

VIII. Disk Organization and File Storage Conventions

Users should be aware of the ability to create directories and subdirectories which enable them to better organize their files. PCs used in common areas should be set up so that each user has a different directory under his/her own name to store data files and other large documents.

The use of file extensions within file names to further identify files is recommended (i.e., "training.doc" might indicate to a user that this file is a document or text file, whereas "training.dat" might indicate that the file is a data file which is in non-readable format).

Some standard file extensions are recommended as follows:

filename.mem (memos), filename.ltr (letter), filename.doc (documentation), filename.lst (lists), filename.tmp (temporary files), filename.pf (primary merge file), filename.sf (secondary merge file), and filename.msg (mail messages)

PC users should refer to software reference manuals to become familiar with automatic extensions appended by certain commercial software packages. This familiarity will help facilitate identification of data files versus required system files and will help avoid erroneous file deletions, for example while cleaning file directories.

IX. Backups/Disaster Recovery

Unfortunately, most computer users learn from a bad experience that backups are critical to information security. Certain EPA systems require routine backups of data. Procedures for creating these backups are documented separately, in the manual written for the system. Most computer applications, however, provide relatively crude backup utilities which do not guarantee the user that their information will be secure; these applications, such as WordPerfect, will create a backup file of each document the user creates but this file is overwritten every time a new file is created. The key to really secure backups is to make a copy of your information and store it on separate media, in a different, preferably remote, location.

- As a minimal control, make regular backups of all documents or data files. A precise set of criteria for determining how often to make backups cannot be provided - how active the data file is and how long it took to create are key factors to consider.

- Several different means for making backups are available (see APPENDIX B: Disk Storage and Hard Disk/Floppy Disk Backup Options).

- Contact the PC Hotline if there are any special security requirements that need to be addressed.

- Note that most information stored on LAN file servers and remote mainframe computers is backed up automatically, and usually on a daily basis. If information has been stored via this media, information can be restored in most cases, upon request. Contact the Computer Room for more details.

X. Sensitive Data Controls/Password Protection

Varying levels of password protection may be applied to the information we store on magnetic media. Controls are already in place for access to the Region 10 LAN and the EPA mainframe. Software for additional file security, such as encryption or file passwords is available on the market but Region 10 has not purchased such add-on security software. Those who are

interested learning more about the criteria for evaluating information sensitivity or wish to discuss incorporation of advanced security measures should address their initial inquiry to the PC Hotline.

- Computer users must not abuse their password and User-ID privileges. Violators of password protection expose the Agency to unnecessary risk and potential irreparable harm caused by unethical users damaging computer resources, accessing and disclosing sensitive information, or committing other fraudulent acts.

- Users must also be aware of some important facts regarding file management on common-use computers. Files which are erased from a magnetic disk using only the standard DOS "DEL" or "ERASE" commands are not actually erased from the computer disk - they are only marked for deletion. For this reason, until they have been overwritten, they can be "unerased" using commercially available utility programs. Additionally, some software systems use work files that are temporarily stored on disk which are deleted by the system when they're no longer needed, but are still recoverable by utility programs. If a user is working with a confidential file and wishes to ensure that this file cannot be recovered by a utility program, after being deleted, he/she should contact the PC Hotline.

- Log off or otherwise inactivate all computers in between uses.

XI. Information Systems Documentation Requirements

Agency information on magnetic media is typically accessed via either a commercial software package, such as WordPerfect, or an application developed in-house, such as a dBase budget tracking system. Therefore, it is necessary that users of this information have sufficient documentation to operate the software package or application. Commercial packages are purchased with manufacturer's documentation, and a myriad of other publications are typically available as well, to provide a user with reference information. We must rely on the developer's of our in-house applications to provide comprehensive documentation for use of their systems, in order to ensure that those for whom the system is intended will be able to get to the agency information they require. It is essential that all new applications developed in the region for manipulation of agency data abide by strict development guidelines:

- Document functional requirements (needs) analysis

- Document system specifications

- Maintain hard copies of program code

- Document all code to explain logic

- Provide comprehensive user documentation and quick reference sheets

- Provide training (optional)

The name of the person to contact for additional guidance regarding information systems documentation may be ascertained by contacting the PC Hotline.

XII. Region 10 Computer Monitoring Procedures

The Region 10 Information Management Branch has implemented control procedures to monitor the effectiveness of the guidelines stated within this document. They are as follows:

1. Inventory Audits

IMB will perform random inventory audits of all computer hardware and software owned and installed in the Region. All discrepancies and violations of regional/software licensing policies are noted and reported for further action. All hardware tracked by the personal property system will be located and sighted by responsible custodial officers annually. Board of survey proceedings will be initiated on any equipment determined to be missing. Movement of all computers and peripherals is to be tracked through move slips.

2. Software Usage Monitoring

IMB will also collect statistics on software accessed by LAN workstations to ensure that only approved software is used on Region 10 computers. This information will help IMB assess regional software support requirements.

3. LAN Environment Monitoring

The Region 10 LAN environment is continuously monitored by software which enables detection of numerous hardware, software or electrical problems that might adversely affect our computing environment.

4. PC Hotline Support Services

Through the PC Hotline, IMB provides regional PC users with a wide range of services to help protect and maintain our computer environment. Services include virus scanning, acquisition of equipment cleaning agents, training on proper hardware/software management procedures, disk management software utilities and disk conversion hardware, etc. Please find additional information on IMB support services in Appendix B: Disk Storage and Hard Disk/ Floppy Diskette Backup Options.

5. Divisional PC Coordinators

Each Division has appointed a PC Coordinator to help manage and control the computer hardware and software. Responsibilities of these coordinators include attendance at monthly PC management meetings, communication between IMB and division management, enforcement of Region 10 Computer Policy, review of inventory reports and oversight of all PC/LAN related division-wide projects.

For further information about Region 10 computer monitoring controls, contact the Information Management Branch.

APPENDIX A

REGION 10 INFORMATION MANAGEMENT CONTACTS

Jane S. Moore
(Senior Information Resource Management Official) X4858
Assistant Regional Administrator for Policy and Management

Robin Gonzalez (PC Site Coordinator). X2977
Chief, Information Management Branch (IMB)

Gus Parlier X2988
Chief, Information Technology Section, IMB

(Vacant). X1605
Chief, Information Services Section, IMB

Sharon Nickels. X6644
PC Hotline Coordinator

Tom Denning X1026
Local Area Network (LAN) Administrator

Julienne Sears
Head Librarian, Region X Library, IMB X2969

Computer Room X4252

PC Hotline X1201
PC Hotline Help Desk - N.E. Corner 8th floor
WPO Id: PCHOTLINE

APPENDIX B

DISK STORAGE AND HARD DISK/FLOPPY DISKETTE BACKUP OPTIONS

DISK STORAGE OPTIONS:

There are four different storage areas where data can reside and they are as follows:

- Floppy diskettes (3.5" or 5.25")
- PC local hard disk
- LAN file server
- Mainframe Storage - DASD (accessed via Arbiter or SEND utility, described below)

The main considerations in choosing a storage area are security, frequency of access, and convenience. Confidential files must not be stored on the Region 10 LAN servers or on single user PCs unless specifically approved in writing by the Director, OIRM. Such data must be stored on diskettes. Sensitive information can be stored on the IBM 3090 mainframe. All information that is accessed by more than one user should be stored on the LAN or mainframe depending on the application. Other types of information can be stored on the PC local hard drive, if one exists, or on floppy diskettes. Please note that PC hard disks and floppy diskettes must be backed-up by the individual user to ensure data integrity. Other factors to consider when choosing between hard drives and floppy disks are as follows:

Error Rates: Hard disks may unexpectedly "crash" (the disks become unreadable) and chances are great, in this case, that all data will be lost. Floppy disks may also "crash". However, the amount of data lost is significantly less than that which is on the hard disk.

Vulnerability: Floppy disks are more susceptible to physical damage while hard disks are protected by the CPU casing.

Security: There is typically no method available on a PC to prevent any user from reading all data on a local hard disk. Floppy disks may be stored in a secure area, and the LAN file server user directories are password protected.

Cost: It is most economical to use central file server storage for installation of major software packages, applications and large data files.

Portability: Floppy disks are portable; hard disks are not easily removable, and therefore not portable. Data stored on the local area network can be accessed from any location in the regional office.

Access Time: Reading or writing to a hard disk is faster than floppy disk access time. Access time is an important consideration when working with either large files or when making frequent alterations to a file of substantial size.

Organization: Hard disk and file server user directory storage should be organized such that user files are separated from standard software and application files. Preparation of

directories to organize all information stored on the hard disk or file server is mandatory due to the size and varied uses of the hard disk. The user has more control over the floppy disk, due to its relatively small storage capacity, so that creation of directories is not essential.

HARD DISK AND FLOPPY DISKETTE BACKUP OPTIONS:

There are four PC hard disk and two floppy diskette backup options and they are as follows:

From PC Hard Disk to Floppy Disk:

The entire disk or portions of it may be copied to high density floppy disks for backup purposes. This option is available to all users; however, it may be very time consuming and should be employed to back up only those files which have been altered. Use of software such as "FASTBACK" will expedite this process. Please contact the PC Hotline to borrow FASTBACK software.

From PC Hard Disk to LAN File Server Hard Disk:

Portions of the disk may be copied to the LAN via the LAN NCOPY command. This option is available to all users that have sufficient LAN disk space available to them in their user directory. The majority of LAN users are limited to 3-6 MB depending on the file server being accessed. From PC Hard Disk to Mainframe DASD: The entire disk or portions of it may be copied to mainframe DASD via ARBITER. This option is available to all users that have active mainframe User-IDs. Special device drivers are also required for the PC and are to be included in the CONFIG.SYS file on the hard disk. If a large volume of data (2 MB or more) is to be backed-up, the procedure is to be run after 5 p.m. so that the network will not be overloaded. Please contact the PC Hotline to obtain the software and procedures for accessing ARBITER.

From PC Hard Disk to Centralized Tape Backup Unit using Local Backup and Restore System:

The entire hard disk may be backed up to a tape, similar to a video recording tape, using a backup tape unit and the Local Backup and Restore System. This will occur in background mode so you continue to use the PC while the backup is occurring. The system is accessed through Miscellaneous Software on the AutoMaxx menu. Further assistance may be obtained in the Computer Room.

From Floppy Disk to Floppy Disk:

This option should be used to back up all information stored on floppy disks. The user has the choice of using the DOS "diskcopy" command (to both format and exactly replicate the data on a disk), or the DOS "copy" command.

From Floppy Disk to LAN File Server Hard Disk:

The entire floppy disk may be copied to the LAN via the LAN NCOPY command. this option is available to all users.

Please consult the PC Hotline, at X1201, to obtain information about any of these options.

QUICK REFERENCE SHEET FEBRUARY 1993

COMPUTER SECURITY POLICY
SUMMARY

Excerpted from the Region 10 Computer Security Policy Manual (February 1993):

Physical Controls

Install computers on stable desk tops with proper ventilation. Turn PCs off each night. Do not move the PC yourself. Call PC Hotline to arrange moving. Label all manuals; store near the PC to facilitate reference. Do not modify physical configuration of equipment.

Software Copyrights/Licenses and Master Copies

Duplication of software for use on another computer is a violation of the license agreement and is considered theft of government property.

Unauthorized Use of Computers

PC games and other non-work related software are strictly prohibited from being installed and/or executed on EPA computers.

Non-EPA Software Product Controls

Software products other than those offered on Agency contracts are generally not permitted on Region 10 PCs. IMB approval and mandatory virus-scanning is required before any non-EPA software can be loaded on an agency computer.

Computer Viruses

A computer virus, much like a human virus, can be transferred from an infected source to any type of disk via many channels. Users who strictly adhere to software license agreement and non-EPA software policies will greatly decrease exposure to virus infection.

Magnetic Media (Information Storage) Controls

Keep disks away from magnetic fields. Do not bend, touch, or write on diskettes. Store disks in their jackets when not in use. All information accessed by more than one user is to be stored on the LAN or mainframe depending on the application. Confidential data must not be stored on the LAN.

Disk Organization and File Storage Conventions

Create directories and subdirectories on the PC hard disk as well as floppy disks for better organization and retrieval of files. The use of file extensions within file names to further identify files is recommended.

Backups/Disaster Recovery

The key to really secure backups is to make a copy of information and store it on separate media, in a different, preferably remote, location. Several different means for making backups are available. Information stored on the LAN or mainframe can be restored in most cases, upon request.

Sensitive Data Controls/Password Protection

Password protection for certain documents or personal computer systems may be established. If there is a need for limited user access to certain information files, call the PC Hotline.

APPENDIX C

QUICK REFERENCE SHEET

DOs AND DON'Ts TO PROTECT YOUR INFORMATION!

MOST COMMON THREATS:	DO	DON'T
Computer Viruses	· Virus Scan all new, non-EPA software · Report any symptoms of viruses to the PC Hotline at once · Avoid use of non-EPA software (i.e. public domain)	· Violate copyright laws
Dust/Dirt	· Clean drive heads	· Leave disks uncovered
Carelessness	· Backup to floppy disk · Set up automatic backup features (such as available in WordPerfect) · Organize sub-directories and use consistent file naming conventions	· Store important information in the share directory on the LAN · Exceed normal storage limitations on disk (75%-80% full is optimal) · Delete or overwrite files in haste
Lack of Knowledge	· Attend basic computer training seminars	· Be afraid to ask for help
Sabotage	· Password protect sensitive information · Report suspicious incidents	· Share your password with ANYONE

CONTACT THE PC Hotline FOR ADDITIONAL INFORMATION OR ASSISTANCE: X1201

Region 10 Electronic File Management Guidance

The following guidance is backed by the philosophy that each system user is responsible for the data that they have generated on the hard disk drive (c:drive) and the LAN user area (f: drive).

That responsibility includes the routine practice of maintenance and cleanup for all of the files that they generate on the system. Disk maintenance and cleanup consists of deleting excess files, assuring that the data is current and making back-ups of important agency data and/or records.

Hard Disk Drive (c: drive) Maintenance

The Information Resources Unit (IRU) will assist users in performing routine maintenance on all existing hard drives by:

* Provide backup hardware and software
* Providing information and clinics on cleaning up harddisk drives
* Providing software for file defragmentation
* Cleanups will be done on a regular (monthly) basis and will be performed by the users.

File Server File (f: drive) Maintenance

The IRU provides tape backup of all data files and E-mail generated on the LAN on a nightly basis. Because of the large volume generated, E-mail data is only kept for one day before being overwritten. All other data files are kept for 2 months before being overwritten which includes all data on the f: drive.

Although this backup process is automatic, it does not automatically delete any files that may not have been touched for a long period of time. The decision to delete files from the user area on the server (f: drive) is left up to the user. IRU requests that users review the files in their user area periodically and delete files that are no longer used and save seldom used files to a floppy disk. IRU will assist in providing users with the necessary tools and techniques to perform routing maintenance on their LAN user areas.

Cleanups will be done on a regular (monthly) basis and will be performed by the users.

Backing-Up Data

Making copies of important data files (especially on your c: drive) is critical to assuring the agency's data is secure and useable if there should be a system crash. The IRU will assist users in obtaining the necessary equipment to backup up large data sets (100mb and greater) on an as-needed basis. Most files can be backed up and stored on floppy disk (1.44mb). Users should regularly make backup copies of important files, label them appropriately and store them in a secure location (at least one other person and the users supervisor should know where to look for the backups).

File and Directory Naming Conventions

It is suggested that all Region 10 system users begin using the following file naming conventions:

Suggested FILE extensions

* doc - general document
* ltr - Agency letter
* rec - Agency Record
* rpt - Agency report

Suggested DIRECTORY names (c: drive only)

* \temp - (standard) Reserved for temporary files (delete once copied to another area)
* \records - for storing Agency record files
* \HQ - for storing any incoming files from HQ
* \Contract - for storing Contractor files
* \Site\Sitename - for storing site files

Date of Last Update: 11/09/95
Person Responsible: Robin Gonzalez
Phone Number: (206) 553-2977

REGION 10
Guidelines and Protocol for sending, receiving and using Electronic Information

The intent of this memo is to provide the Region 10 staff with a framework for working with and using electronic mail (E-mail) and electronic information sources such as the Internet or electronic Bulletin Board Systems (BBS). The same "Business Communication Protocol" that applies to our existing methods of written communication and distribution also applies when sending, receiving, searching or using electronic information.

Electronic communications are subject to the same records management considerations as printed communications. The nuances of "what are records" are not discussed here, but any communication that announces an agency decision or policy is an official record. Each user is responsible for managing records that they originate. The Information Resources Unit does not maintain backups of E-mail and therefore cannot provide copies of messages in response to FOIA requests.

Any of the various means of processing electronic information may only be used for the purpose of conducting Official Agency business. "Official Agency business" can be defined as any correspondence relating to the mission and/or authorized objectives of EPA, including actions or programs sanctioned by the Administrator or Regional Administrator. Use of government equipment and communications channels to send and/or to receive information of a personal nature is prohibited and can be career limiting.

Electronic Mail (E-mail)

For the purposes of this document the term "E-mail" refers to any Agency E-mail program including WPO, GroupWise, Lotus Notes, All-in-One or cc:Mail.

Be aware that there are situations in which E-mail is not an appropriate communication tool, such as Official Agency correspondence or any documents which require a signature.

EPA policy prohibits the availability of confidential or sensitive material on the LAN, which includes E-mail. If you have a need to send this type of information via E-mail, be sure to use the security features available. Once sent, the message must be deleted from the LAN. If it needs to be saved, it should be stored on a floppy diskette and placed in a secure location.

Any EPA employee needing to send an all-employee broadcast message (i.e., using the REGX for all of Region 10 including Operations Offices or SEA group), should check beforehand with their supervisor or the appropriate program manager for specific policies. Limiting the authority to approve broadcast messages to a small group of people

is a prudent practice which will enable better control over the information that is distributed on a wide scale.

Any recipient of an E-mail message that is not appropriate or does not conform to these guidelines, should forward the message along with their comments to the sender, and a cc: to the senders' supervisor. If the message is overtly threatening or inappropriate because of vulgar language or content, the recipient should notify their supervisor or the HR officer immediately.

Each LAN user is responsible for maintenance of his or her own IN and OUT Mailboxes. There is a limit of 500 messages that can be retained in either area. A full IN box will prevent anyone from sending in more mail, and the recipient will not be aware of this problem. Therefore, it is important that mail messages be deleted and/or stored elsewhere on a frequent basis. It is recommended that users make decisions regarding the deletion or storage of messages immediately upon reading them. Clean up your "in" and "out" mailboxes and folders on a weekly basis so as to keep the system clear of any unnecessary files.

Messages older than 60 days and which are not stored in an archive folder are automatically deleted by the system. Further information regarding maintenance of your mailbox messages may be obtained from the PC HOTLINE (x1201).

Messages being sent to Field offices with files attached are to be limited to 100 kilobytes in size (approximately 50 pages or a 1 page graphic). Contact the PC HOTLINE if you are not sure how to determine file size. This practice will prevent excessive delays in mail delivery to those offices.

There is an "auto-delete" send option available that should be used for messages that have a specific time value on them (e.g. appointments, meetings, etc.). This will save time for those who have been out of the office for some time and do not want to have to comb through a pile of "old mail." Remember to use this feature when sending time sensitive messages. E-mail messages may be sent over the Internet using any of the above mentioned standard E-mail programs. This option should only be used if any of the other options are not available to either party involved (such as with outside vendors or contractors that do not have access to our mail systems).

Internet
For purposes of this document the terms World Wide Web (WWW), Gopher, File Transfer Protocol, Telnet and Worldwide Area Information Search(WAIS) are synonymous with Internet.

The Internet may be used for the purpose of seeking and using pertinent information related to environmental protection as it applies to your position description and areas of responsibility.

We encourage Internet users to use the search engines provided and index on the topic that you are seeking to know more about. This will save the Agency time and money.

Please be aware that Internet "traffic" is monitored by the telecommunications services group at RTP. If suspicious sites are being visited that are clearly not work related, there is a good chance that your supervisor may receive a call to discuss the problem. Again, abuse of this resource can be career limiting, so don't get sidetracked in an undesirable cyberhood.

Bulletin Board Systems (BBS's)
Bulletin Board Systems may be used for the purpose of seeking and using and posting pertinent information related to environmental protection as it applies to your position description and areas of responsibility.

The BBS it intended to be an outreach vehicle to the public who have a means of communicating via a modem. We encourage you and your colleagues to use the BBS for posting important topics or meetings that are open for public input.

One note of caution regarding files on the BBS: Files posted in conference areas are accessible by all BBS users. Therefore, when sending files to a specific BBS user (not intended for general consumption), the file attachment feature in BBS mail should be used, otherwise the document will be posted for all to read.

The same protocol that applies to E-mail should be observed when responding to an inquiry on the BBS.